UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE AGENUS INC. SECURITIES LITIGATION	**Case No. 1:24-cv-12299-AK** **CLASS ACTION**
THIS DOCUMENT RELATES TO: *ALL ACTIONS*	**AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

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GLOSSARY OF DEFINED TERMS

Term	Definition
2022 10-K	Annual financial report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 16, 2023 and signed by Defendants Armen and Klaskin
2022 Call	A March 16, 2023 call with investors and analysts during which Defendants' reviewed Agenus's performance in fiscal year 2022
2022 Release	Agenus's March 14, 2023 press release announcing the Company's Q4 and full year 2022 financial results
2023 10-K	Annual financial report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 14, 2023 and signed by Defendants Armen and Klaskin
2023 Call	March 14, 2024 earnings call with investors and analysts to discuss Agenus's Q4 and full year 2023 results
Abrams	Agenus Chief Legal Officer Robin Abrams
Agenus	Defendant Agenus, Inc.
Armen	Defendant Garo H. Armen, Agenus's CEO at all relevant times.
ATM	At the market stock offering
BAL Withdrawal Release	October 22, 2021 press release issued by Agenus announcing that the FDA had forced it to "voluntarily" withdraw a BLA for balstilimab
BLA	Biologics License Application
BOT/BAL	Unless otherwise indicated, the use of a combination of botensilimab and balstilimab to treat of patients with non–microsatellite instability–high (MSI-H)/mismatch repair–deficient (dMMR) metastatic colorectal cancer (mCRC) with no active liver involvement.
Brown	Agenus Senior Director of Data Science Kris Brown
Buell	Jennifer Buell, President and CEO at Agenus's subsidiary, MiNK Therapeutics, and the Chairman, Executive Council at Agenus
CEO	Chief Executive Officer
ClinTrial Pro	Clinical trial vendor ClinTrial Pro Inc., which was contracted by Agenus to assist with clinical trials of BOT/BAL

CMC	Agenus's Chemistry, Manufacturing, and Controls Department
CMO	Chief Medical Officer
Colburn	Dawn Colburn, Agenus's Vice President of Clinical Science from October 2022 through May 2023
Company	Defendant Agenus, Inc.
CW	Confidential Witness
dMMR	Mismatch repair deficient
DeSander	Chief Business Officer Julie Desanders
EOP2 Meeting	July 2024 meeting between the FDA and Agenus to discuss Accelerated Approval of BOT/BAL
EOP2 Release	A press release issued during pre-market hours on July 18, 2024 entitled "Agenus Announces End-of-Phase-2 Meeting Outcomes and Topline Interim Phase 2 Data for BOT/BAL in MSS Colorectal Cancer"
Fagan	Agenus Chief Communications Officer Stephanie Fagan
FDA	U.S. Food & Drug Administration
GMP	Good manufacturing practices
Gottam	Krishnaveni Gottam, Agenus's GMP QA operations site head, who worked at Headquarters.
Grossman	Joseph Grossman, Agenus's Vice President of Early Clinical Development
Headquarters	Agenus's principal executive offices, which are located at 3 Forbes Road, Lexington, Massachusetts 02421
Humes	Eric Humes, Agenus's Chief Quality Officer who reported to Defendant O'Day.
Hurley	Agenus Clinical Operations Head Randy Hurley
IMM	Irreversible morbidity or mortality
King	Sara Ashworth King, Manager, Quality Assurance Doc Control at Agenus
Klaskin	Defendant Christine M. Klaskin, Agenus's VP of Finance at all relevant times.
Mach	Agenus project manager Linh Mach
MMR	Mismatch repair

MSI	Microsatellite instable
MSI-H	Microsatellite instability high
MSS	Microsatellite stable
O'Day	Defendant Steven J. O'Day, Agenus's Chief Medical Officer at all relevant times.
ORR	Overall response rate
Patel	Jaymin Patel, Agenus's Executive Medical Director/Head of Biomarkers from October 2021 to December 2022, and Agenus's Vice President of Translational Research from January 2023 through August 2024.
Paul	Jijo Paul an independent consultant for Agenus owned clinical trial vendor ClinTrial, which worked on BOT/BAL clinical trials
Q1 2023 10-Q	Quarterly financial report on Form 10-Q for the quarterly period ended March 31, 2023 was filed with the SEC on May 9, 2023 and signed by Defendant Klaskin
Q1 2023 Call	May 9, 2023 earnings call with investors and analysts to discuss Agenus's Q1 2023 results
Q1 2024 10-Q	Quarterly financial report on Form 10-Q for the quarterly period ended March 31, 2024 was filed with the SEC on May 7, 2024 and signed by Defendant Klaskin
Q1 2024 Call	May 7, 2024 earnings call with investors and analysts to discuss Agenus's Q1 2024 results
Q2 2023 10-Q	Quarterly financial report on Form 10-Q for the quarterly period ended June 30, 2023 was filed with the SEC on August 8, 2023 and signed by Defendant Klaskin
Q2 2024 Call	May 8, 2023 earnings call with investors and analysts to discuss Agenus's Q1 2023 results
Q3 2023 10-Q	Quarterly financial report on Form 10-Q for the quarterly period ended September 30, 2023 was filed with the SEC on November 9, 2023 and signed by Defendant Klaskin
Q3 2023 Call	November 7, 2023 earnings call with investors and analysts to discuss Agenus's Q3 2023 results
Q3 2024 Call	November 12, 2024 earnings call with investors to disclose Agenus's financial performance for the third quarter of 2024

Rosenthal	Katherine Rosenthal, Agenus's Director Clinical Program Management from May 2021 through November 2023
Savitsky	David Savitksy, a current Agenus Director in Pre-Clinical Development
SGDA	Senior Global Clinical Development, Medical Affairs, and Commercial Advisor
Song	VP of Biostatistics and Data Management James Song
Sponsor	A company seeking FDA approval of a drug or treatment
VP	Vice President
Winter	Craig Winter, Agenus's Chief Information Officer
Yancey	Todd Yancey, Agenus's SGDA
Zahora	Judyth Zahora, Agenus's Senior Director of GCP Quality Risk Management & Process Improvement

Lead Plaintiff Byron Olsen ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's Amended Complaint against Defendants Agenus Inc. ("Agenus," or the "Company"), Garo H. Armen ("Armen"), Christine M. Klaskin ("Klaskin"), Steven J. O'Day ("O'Day") and Todd Yancey ("Yancey," and, together with Agenus, Armen, and Klaskin, "Defendants"), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by Plaintiffs' counsel, which includes among other things: (a) review and analysis of regulatory filings made by Agenus with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) research reports prepared by securities and financial analysts concerning Agenus; (c) transcripts of Agenus's investor conference calls; (d) Agenus's investor presentations; (e) reports by the financial press concerning Agenus; (e) Agenus securities pricing data; (f) interviews of former Agenus employees; (g) consultations with experts; and (h) other material and data identified herein. Lead Counsel's investigation into the factual allegations is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Plaintiffs believe that substantial additional evidentiary support exists for the allegations herein and will continue to be revealed after Plaintiffs have a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities fraud class action on behalf of a class consisting of all persons and entities, other than Defendants and their affiliates, who purchased or otherwise acquired Agenus securities between January 23, 2023 and July 17, 2024, both dates inclusive (the "Class Period"). Plaintiff seeks to recover on his behalf and on behalf of the Class (as defined herein) damages caused by Defendants' violations of the federal securities laws and to pursue remedies

under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. This action arises out of false or misleading statements by Defendants, Agenus's CEO, VP Finance, CMO, and SGDA. Throughout the Class Period, Defendants made multiple material misrepresentations and omissions concerning Agenus's experimental cancer combination immunotherapy candidate botensilimab and balstilimab ("BOT/BAL").

3. Specifically, Defendants made statements (i) misleading investors as to the likelihood that BOT/BAL would be approved by the FDA as part of the Agency's "Accelerated Approval Program"; (ii) misleading investors as to efficacy and import of the treatment, including the reliability of the rates of durable response (*i.e.*, the percentage of cancer patients who experience a partial or complete response to treatment that lasts for at least six months) and overall survival (*i.e.*, length of time from diagnosis or treatment that a patient remains alive) in clinical trials; and (iii) Agenus's ability to develop or produce treatments, including BOT/BAL on an accelerated timeline. These misstatements also concealed the extent of the material risk that the FDA would not allow Agenus to submit the treatment for accelerated approval. As the truth emerged and the concealed risk materialized, Agenus's share price plummeted ***by over 58%***, devastating investors.

4. Agenus is a clinical-stage biotechnology company that discovers and develops immuno-oncology ("I-O") products in the U.S. and internationally. During the Class Period, Agenus was almost exclusively focused on obtaining Accelerated Approval of BOT/BAL.[1] If the

[1] Unless otherwise indicated, references to "BOT/BAL" herein are to the use of a combination of botensilimab and balstilimab specifically for the treatment of patients with non–microsatellite instability–high (MSI-H)/mismatch repair–deficient (dMMR) metastatic colorectal cancer (mCRC) with no active liver involvement.

treatment was approved, it could fill a massive need in colorectal cancer ("CRC") treatment, as BOT/BAL was purportedly effective on microsatellite stable ("MSS") CRC tumors, which affect approximately 80-85% of colorectal cancer patients, present a higher risk of recurrence, and are more lethal.

5. Approval of BOT/BAL also was essential to Agenus's viability, and the Company's hemorrhaged cash prior to and during the Class Period. In fact, the Company's reported cash and cash equivalents of $307 million as of December 31, 2021 fell 37% to $193 million by December 31, 2022, and fell another 60%, to $76 million, by December 31, 2023. From December 31, 2021 to December 31, 2023, Agenus's ***declined a total of 75%***.

6. The Company's dire financial condition meant that Defendants could not wait for approval of BOT/BAL through the FDA's typical approval process, which could take years. In addition, investors were leery that Agenus could be beaten to the punch by a competitor, which would make BOT/BAL worthless. Indeed, this had happened to Agenus as recently as 2021, when the Company had sought FDA approval for balstilimab alone as a treatment for ovarian cancer. Agenus had been forced to drop the drug when the FDA without warning approved a similar product from Merck.

7. Defendants were so determined not to be trumped a second time that, in August 2023, midway through the Class Period, they laid off 25% of the Company's workforce and ceased development of other treatment candidates to focus on Accelerated Approval of BOT/BAL for MSS CRC and, to a lesser degree, other cancers. Defendant Armen expressly assured investors that "***[b]y zeroing in on BOT/BAL, we expect to expedite regulatory approval and availability for healthcare providers and patients in need***.

8. Defendants knew, however, that the FDA would not grant Accelerated Approval for BOT/BAL unless Agenus provided substantial, reliable evidence of durability and an overall survival benefit, *i.e.*, scientific evidence that BOT/BAL significantly increased the percentage of cancer patients who experience a partial or complete response to treatment that lasts for at least six months and/or significantly increased the length of time from diagnosis or treatment that a patient remained alive. This was because the FDA had had to rescind Accelerated Approval of multiple cancer treatments in the years leading up to the Class Period because subsequent testing showed that the treatments provided little to no survival benefit.

9. Accordingly, Defendants repeatedly (and ultimately misleadingly) touted to investors that Agenus could obtain Accelerated Approval from the FDA for BOT/BAL because the treatment's clinical trials were tailored to the FDA's Accelerated Approval criteria, trials were producing necessary data on durability and overall survival endpoints critical to the FDA's decision-making, the treatment itself was "unprecedented," and the Company had developed internal processes, technology, and expertise were designed to facilitate accelerated approval.

10. For example, Defendants touted to investors that "***advancing in multiple clinical programs which we have designed to support regulatory pathways for accelerated development with botensilimab as a monotherapy and in combination with balstilimab***."

11. Defendants also repeatedly emphasized BOT/BAL's durability and overall survival data, touting that studies "highlight the ***deep and durable responses achieved with botensilimab and balstilimab in advanced MSS CRC,*** underscoring remarkable benefit for these patients who have failed standard of care or other investigative therapies." Defendants further highlighted that "***new data show substantial survival benefits and long-lasting responses***" and insisted that "***we are witnessing unprecedented responses***."

12. Finally, because Accelerated Approval of BOT/BAL was mission-critical for Agenus to be a worthwhile investment, Defendants took pains to assure investors that Agenus was an organization designed to develop its products faster than competitors, and thus was uniquely positioned to obtain Accelerated Approval. To that end, the Company's SEC filings touted that Agenus's "***integrated, end-to-end capabilities . . . together with a comprehensive and complementary portfolio will uniquely position us to produce novel therapies on accelerated timelines***."

13. These and many other statements made throughout the Class Period were not made in a vacuum. Desperate for financing as its cash dwindled, Defendants caused Agenus to participate in multiple at the market offerings ("ATM Offerings") of Agenus shares to reap much-needed capital. Specifically, Defendants had Agenus sell $84.4 million in shares at ATM offerings in 2023, including sales worth $20.3 million in Q2 2023 alone, and $24.4 million in shares in the period of January 1, 2024 through March 8, 2024 for total net proceeds of $149.8 million. The returns to Agenus from the ATM offerings were bolstered by Defendants' statements regarding Accelerated Approval of BOT/BAL—indeed, the 2024 sales were made as Defendants prepared a presentation to the FDA regarding Accelerated Approval and at the same time touted to investors:

- "***the positive trends and lasting responses in our studies strengthen our conviction in BOT/BAL potential***";
- "***I certainly expect that we'd be able to demonstrate a point estimates for response, durability of response for patients with stable disease or better and that is trending toward a survival benefit***";
- "***I think we have a very, very robust set of data to present to the agencies***";
- "***do overall response rates translate to longer-term benefit. We know they do***."

14. According to multiple CWs, however, but unbeknownst to investors, Agenus lacked the data necessary to obtain Accelerated Approval of BOT/BAL, and Defendants knew it.

Specifically, Agenus's clinical trial data from Phase 1 and Phase 2 trials were from too small a sample size and too short a trial period to demonstrate durability or a survival benefit. Indeed, Defendants' Phase 1 trials were not powered appropriately to capture survival or durability data. Multiple executives at Agenus, including the Company's FDA submission team, confronted Defendants with the fact that their data was insufficient to obtain Accelerated Approval, but Defendant Armen, Agenus's CEO, retorted, "***who cares about FDA, they can't stop us***" and "***we're going to submit with what we have because this is a breakthrough and they should not deny it.***"

15. The CWs further described how Defendants had been warned repeatedly about making statements about the "unprecedented" nature of BOT/BAL and the import of the durability and overall survival rates, which were not supported in Phase 1 and Phase 2 trials. Defendants, however, ignored that advice and fired the employees soundings the alarms.

16. Finally, the CWs revealed that Agenus lacked the operational capability of accelerating any development process both because Defendants' development plans were made up out of whole cloth, unsupported, unachievable, and forced down employees' throats, and because Agenus routinely failed to pay vendors, which resulted in manufacturing stoppages.

17. Since investors were kept in the dark about the extent of the risk that BOT/BAL would not receive Accelerated Approval, the fact that the Phase 1 and Phase 2 clinical trial data did not support Defendants' rosy descriptions of BOT/BAL, and Agenus's operational inability to accelerate a drug development timeline, they were stunned when the Defendants statements were revealed to be false and misleading, and the risks concealed by those statements emerged on July 18, 2024.

18. Investors had known for weeks that Defendants were going to participate in a July "end-of-Phase 2" ("EOP2") meeting with the FDA to discuss a forthcoming application for Accelerated Approval of BOT/BAL, among other things. On July 18, 2024, Defendants issued a press release ("EOP2 Release") revealing that the FDA had advised ***against*** an Accelerated Approval application for BOT/BAL because Defendants' Phase 2 data "may not translate to survival benefit."

19. The EOP2 Release also revealed a number of facts that blind-sided investors. First, interim topline data from the Phase 2 study showed that patients treated with the 75-mg dose of BOT/BAL experienced an "overall response rate" ("ORR") of 19.4%, and patients given the 150-mg dose of BOT/BAL experienced an ORR of only 8.2%, even though there was no evidence of toxicity from the higher dose and the maximum-tolerated dose was not reached. This meant that a 150mg dose of BOT/BAL was less than half as effective as a 75mg dose, even though the larger dose did not harm the patient, and thus threw into serious doubt BOT/BAL's long term effectiveness. Further, the interim Phase 2 data Defendants presented to the FDA was not even complete in an interim sense, as two class members had not participated in the clinical trial long enough for the FDA to credit their data.

20. On this news, Agenus's stock price fell $10.43 per share, or 58.83%, to close at $7.30 per share on July 18, 2024.

21. Two weeks later, on August 8, 2024, Defendants held an earnings call with analysts and investors to discuss Agenus's performance in the second quarter of 2024. During the call, it became clear that Defendants never had a "***robust set of data***" for the FDA and did not know whether "***overall response rates translate to longer-term benefit***." During the call, in response to an analyst's question, Defendant Armen stated that "[w]e are confident that in an immuno-

oncology treatment setting, ***any trial*** that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates ***always translates to survival benefit*** . . . . ***the FDA, I think, need[s] to be schooled in this phenomenon***." In other words, Defendants ***had assumed the existence of a survival benefit*** from Agenus's BOT/BAL data. Accordingly, Defendants did not have data demonstrating an overall survival benefit for the meeting with the FDA.

22. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

23. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

25. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Agenus is headquartered in this District, Defendants conduct business in this District, and a significant portion of Defendants' actions took place within this District.

26. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

27. Plaintiff, as set forth in the attached Certification, acquired Agenus securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

28. Defendant Agenus is a Delaware corporation with principal executive offices located at 3 Forbes Road, Lexington, Massachusetts 02421 ("Headquarters"). The Company's common stock trades in an efficient market on the Nasdaq Capital Market ("NASDAQ") under the ticker symbol "AGEN."

29. Defendant Garo H. Armen ("Armen") co-founded Agenus in 1994 and has served as the Company's Chief Executive Officer ("CEO") and Chairman since its founding and as a Company director since 1999 and was Agenus's CEO at all relevant times. Defendant Armen also served as a member of Agenus's Executive Committee at all relevant times.

30. Defendant Christine M. Klaskin ("Klaskin") has served as Agenus's Vice President ("VP") Finance since October 2006, and was the Company's VP Finance and Principal Financial Officer at all relevant times.

31. Defendant Steven J. O'Day ("O'Day") has served as Agenus's Chief Medical Officer ("CMO") at all relevant times.

32. Defendant Todd Yancey ("Yancey") was Agenus's Senior Global Clinical Development, Medical Affairs, and Commercial Advisor ("SGDA") from at least November 2023. Yancey is currently a member of the Company's "advisory board."

33. Defendants Armen, Klaskin, O'Day, and Yancey are collectively referred to herein as the "Individual Defendants."

34. The Individual Defendants possessed the power and authority to control the contents of Agenus's SEC filings, press releases, and other market communications. The

Individual Defendants were provided with copies of Agenus's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Agenus, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

35. Agenus and the Individual Defendants are collectively referred to herein as "Defendants."

36. Defendants are liable for: (i) making false statements; (ii) failing to disclose adverse facts known to them about Agenus; and (iii) engaging in a scheme to defraud. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Agenus's securities was a success, as it: (i) deceived the investing public regarding the truth about Agenus's business operations and financial prospects; (ii) artificially inflated the prices of Agenus's securities; and (iii) caused plaintiff and other members of the Class to purchase Agenus's securities at inflated prices.

CONFIDENTIAL WITNESSES

37. CW1 was a Quality Assurance Document Control Specialist with Agenus from February 2023 until March 2024, when his role was eliminated in a round of layoffs. CW1 worked at Agenus's Headquarters and reported to Judyth Zahora, Agenus's Senior Director of GCP Quality Risk Management & Process Improvement from December 2020 to May 2024 ("Zahora"). Zahora reported to Eric Humes, Agenus's Chief Quality Officer ("Humes"), who CW1 believes reported to Defendant O'Day. CW1 was responsible for quality assurance in document control and

managed paper and digital documentation created by the Company, from vendor contracts to clinical trial results. CW1 helped to process, store, and archive records both digitally through ZenQMS, the company's electronic quality management system, and physically in the company's fire-proof archive on the first floor of Headquarters. CW1 also helped to process batch document requests from internal departments such as the manufacturing team or from the FDA in the event of an audit.

38. CW2 was a Clinical Trial Associate contractor with Agenus from January 2023 to September 2024, when he was laid off. CW2 worked remotely from Southern California and reported to Jijo Paul ("Paul"), an independent consultant for Agenus whose company, ClinTrial Pro Inc. ("ClinTrial Pro") was contracted by Agenus to assist with BOT/BAL clinical trials. CW2 was responsible for coordinating documentation of Agenus's Phase 1 trials of the BOT/BAL combination therapy on CRC. CW2's work was performed in preparation for Agenus's planned submission of data to the FDA in the first quarter of 2024, and included checking documents to ensure they were complete, monitoring and screening cohort enrollment numbers, and coordinating with clinical sites that were screening patients for submission into the trial.

39. CW3 was a Senior Director, Field Medical Science Liaisons at Agenus from May 2023 through December 2024, when he was laid off. CW3 reported to Agenus's Vice President of Medical Affairs, and worked remotely from Narberth, Pennsylvania and supervised eight Medical Liaisons across the East Coast. CW3 has 18 years of experience in the pharmaceutical industry working for multiple pharmaceutical companies. CW3 and his team was responsible for generating external expert interest in the science behind the BOT/BAL combination immunotherapy. CW3 and his team met with key opinion leaders across the East Coast to introduce them to the treatment and explain the existing data showing the efficacy of the drug.

40. CW4 worked for Agenus from September 2021 through May 2024. Specifically, CW4 was Clinical Trial Medical Monitor/Head of Medical Communications from September 2021 through Apr 2023, Medical Director of Clinical Development from Apr 2023 through December 2023 and Senior Medical Director of Clinical Development from December 2023 through May 2024. CW4 worked at Headquarters, and first reported to Philip Ford, who was a contractor briefly employed in Agenus's Medical Affairs department. CW4 then reported for a short time to Dawn Colburn, Vice President of Clinical Science from October 2022 through May 2023 ("Colburn"), then to Joseph Grossman, Agenus's current Vice President of Early Clinical Development ("Grossman"). Grossman reported to Defendant O'Day who reported to Defendant Armen. CW4 was involved in Phase 1 trials of BOT/BAL for melanoma patients and pancreatic cancer patients.

41. CW5 was the Global Head of Regulatory with Agenus from May to August 2024. CW5 reported directly to Defendant Armen and partially reported to Jennifer Buell, President and CEO at Agenus's subsidiary, MiNK Therapeutics, and the Chairman, Executive Council at Agenus ("Buell"). CW5 working remotely from California but reported directly to Headquarters. CW5 was responsible for the development and execution of regulatory strategy and deliverables for all assets in all stages including Investigational New Drugs, New Drug Applications and Life Cycle Management activities across Agenus's portfolio. He was personally involved in the presentation of BOT/BAL to the FDA, and personally attended the EOP2.

42. CW6 was Associate Director of Clinical Development with Agenus from May 2022 through August 2023, when he was laid off. CW6 reported to Jaymin Patel ("Patel"), Agenus's Executive Medical Director/Head of Biomarkers from October 2021 to December 2022, and Agenus's Vice President of Translational Research from January 2023 through August 2024, who reported to Defendant O'Day. CW6 worked remotely from Los Angeles, California, but flew into

Headquarters about four times a year for meetings. CW6 was responsible for project management of Agenus' Phase 2 trial of BOT/BAL for the treatment of patients with colorectal cancer. He was also project manager for a Population Pharmacokinetics (Pop PK) analysis of botensilimab on various cancers in a Phase 1 trial, and he managed Phase 1 study of another drug that was eventually tabled by the company. As the project manager for the Phase 2 trial of BOT/BAL for CRC, CW6 was responsible for the planning, execution, and oversight of academic studies related to the drug. He also coordinated and oversaw about 20 people who led clinical trial tasks such as site selection, patient recruitment, data collection, analysis and reporting, as well as patient safety.

43. CW7 was the Senior Vice President for Global Medical Affairs and Product Strategy with Agenus during the middle of the Class Period and reported directly to Defendant Armen. CW7 led the team that was responsible for communicating study data to key opinion leaders in the field of CRC and ensuring that those leaders were aware of that data. CW7 also personally met with physicians and key opinion leaders. His Medical Affairs team was responsible for addressing any questions from leaders in the field about the drug and bringing ideas generated from those conversations to be considered in-house.

44. CW8 was the Vice President of Global Head of Clinical Operations with Agenus from May 2022 through May 2023, when he was laid off. CW8 reported directly to Defendant Armen. CW8 was responsible for managing trial program level responsibilities, such as budget, timeline, and drug supply management and forecasting. He also led supporting efforts in the planning, execution, oversight, and reporting of all phases of clinical trials, including specifically for Phase 2 trials of BOT/BAL for CRC.

45. CW9 was Agenus's Vice President of Research Computing and Data Science from September 2021 through November 2022. CW9 initially reported to Buell from September to

October 2021, who was Agenus's Chief Operating Officer at the time, then directly to Defendant Armen, then to Chief Information Officer Craig Winter ("Winter") during his last year at Agenus.

SUBSTANTIVE ALLEGATIONS

A. Colorectal Cancer and Microsatellite Stable Tumors

46. Colorectal cancer ("CRC") is the most common gastrointestinal cancer and the third leading cause of cancer-related death in humans.[2] In fact, while CRC in the late 1990s was the cancer that caused the fourth-most deaths in both men and women younger than 50, it is now the cancer that causes the most deaths in men and second-most deaths in women.[3] Patients with metastatic CRC have a life expectancy of approximately only 30 months.[4]

47. CRC tumors have an "MSI status," and are either microsatellite instable ("MSI") or MSS (microsatellite stable). A normal cell uses a process called mismatch repair ("MMR") to fix errors like mutations that can happen when DNA divides and makes a copy of itself. If a cell's MMR system is not functioning properly, however, errors will build up and cause the DNA to become unstable, or MSI. Depending on the type of test used, an MSI tumor or may be identified by the interchangeable terms microsatellite instability high ("MSI-H") or mismatch repair deficient ("dMMR"). MSI tumors, or "hot" tumors, trigger a strong response from the body's immune system.

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[2] Rebecca L. Siegel, *Cancer Statistics, 2021*, Jan. 12, 2021, https://pubmed.ncbi.nlm.nih.gov/33433946/.

[3] Rebecca L. Siegel, *Cancer Statistics, 2024*, Jan. 17, 2024, https://pubmed.ncbi.nlm.nih.gov/38230766/.

[4] Ibrahim Halil, *Immunotherapy for Microsatellite Stable Colorectal Cancers: Challenges and Novel Therapeutic Avenues*, ASCO Educational Book, Jun. 3, 2022, https://ascopubs.org/doi/10.1200/EDBK_349811#body-ref-bibr1-EDBK_349811

48. MSS tumors, or "cold" tumors, on the other hand, are tumors with stable DNA in tumor cells. Unlike MSI tumors, MSS tumors do not normally trigger a strong response from the body's immune system, are less mutated than MSI-H/dMMR tumors and exist in suppressed immune systems. Not only do approximately 80-85% of colorectal cancer patients have MSS tumors, but patients with MSS tumors also have a higher risk of recurrence. Importantly, MSS tumors generally do not respond to "immunotherapy."[5]

49. Immunotherapy is a collection of cancer treatments that seek to enhance the body's immune system by helping it recognize and combat cancer cells. While the immune system naturally identifies, attacks, and destroys cancer cells (and other abnormal cells), various types of immunotherapies can enhance these functions.

50. For example, "immune checkpoints" are proteins that prevent the body's immune responses from being too strong and damaging healthy cells. "Immune checkpoint inhibitor" immunotherapies block these immune system "checkpoints," which enables immune cells to respond more strongly to cancer cells. Immune checkpoint inhibitors include "PD-1" and "CTLA-4," which are proteins that regulate activity in T cells—a type of white blood cell. Immunotherapy drugs can block PD-1 and CTLA-4, and thereby boost the body's immune response.

51. Immunotherapy targets specific cancer cells rather than healthy ones, and thus is less toxic to the body. This is in contrast to chemotherapy, which can quickly shrink tumors, can also harm healthy cells. It also causes many unpleasant side effects and can lead to a suppressed immune system. In addition, because immune cells travel through the body via the bloodstream and lymphatic system, immunotherapy can treat patients with metastasizing cancer in which

[5] *Id.*

tumors have spread to multiple organs. Immunotherapy thus is particularly effective in later-stage cancers, or on cancers that have not responded well to traditional treatments.

52. As described above, however, immunotherapies generally do not work on MSS tumors because MSS tumors do not trigger a strong immune response. Accordingly, "there is great unmet need in [CRC cancer] management, particularly for those with microsatellite stable (MSS) colorectal cancer."[6]

B. The FDA's Accelerated Approval Process

53. In 1992, the FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, including cancer, and fill an unmet need. The defining features of the Accelerated Approval Program is that it may allow prospective drugs or treatments to be marketed after limited number of "clinical trials" and based on a less rigorous "endpoint."

54. Clinical trials are studies performed on people to assess a potential treatment for a specific disease or condition. There are four separate phases of clinical trials. Phase 1 trials test safety and dosage of a drug, last for several months, and are performed on 20 to 100 volunteers. Phase 2 trials test the efficacy and side effects of a drug, can last from anywhere between several months to two years, and are performed on up to several hundred volunteers. Phase 3 trials test the efficacy of a drug and monitor for adverse reactions to the drug, can least from anywhere between one to four years, and are performed on 300 to 3,000 volunteers. Phase 4 trials test for the safety and efficacy of a drug on several thousand volunteers after the drug has been approved by the

[6] Ibrahim Halil, Immunotherapy for Microsatellite Stable Colorectal Cancers: Challenges and Novel Therapeutic Avenues

FDA. Throughout this process, the FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

55. Clinical trials for cancer treatments employ unique "endpoints," which are results that are measured at certain points during a study and/or at the completion of the study to see if a given medication worked and how safe the medication is. When evaluating a treatment in the Accelerated Approval Program or as part of the traditional path to approval, the FDA uses study endpoints to inform its drug approval decisions and patients/physicians use the same endpoints to inform treatment decisions.

56. One pivotal endpoint in cancer treatments is Overall Survival ("OS"). OS is the average length of time patients are alive after the start of treatment and is measured by how long patients, who undergo a specific treatment regimen, live compared to patients who are in a control group. If a clinical trial demonstrates improved OS it provides evidence of the drug's value in prolonging a patient's life. Given it requires having more patients who are monitored for a prolonged period of time as compared to other clinical trial endpoints, OS is often considered the "gold standard" for measuring the clinical benefits of a cancer drug.

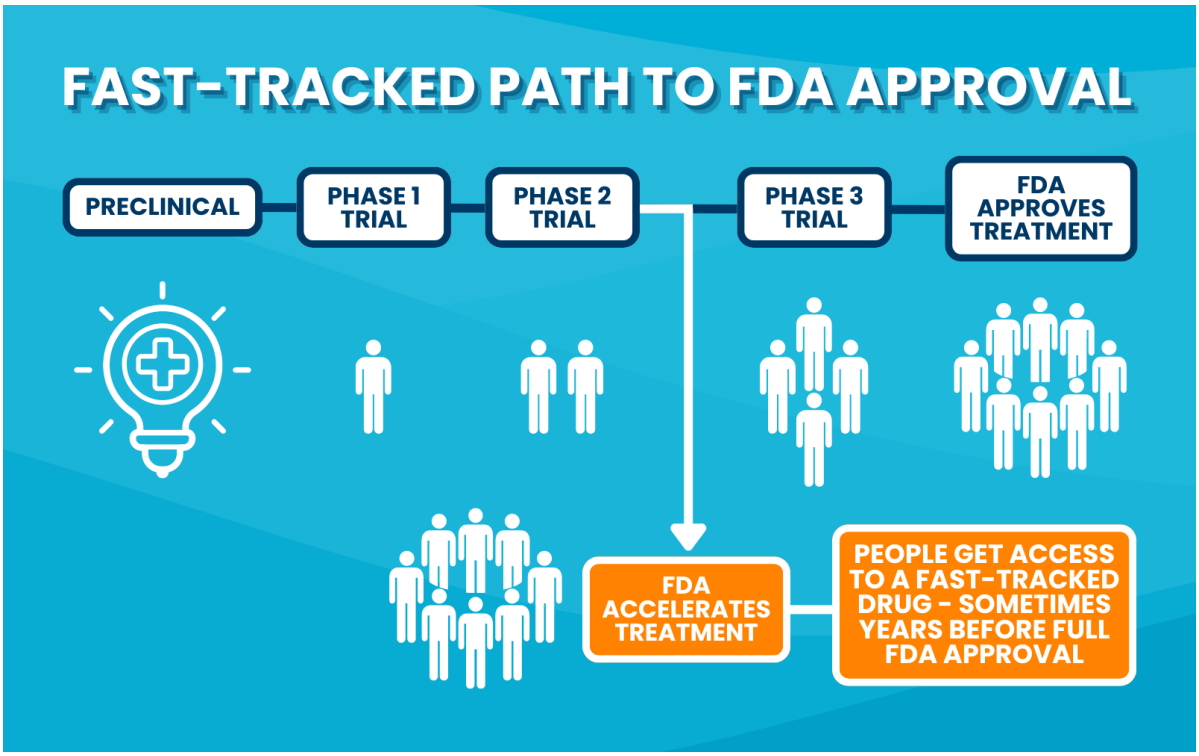
57. Another endpoint, Overall Response Rate ("ORR") is the percentage of patients whose cancer shrinks or disappears after treatment. ORR is measured by adding the number of complete responses, consisting of patients with no detectable evidence of a tumor over a specific time period, and partial responses, consisting of patients with a decrease in tumor size over a specific time period. Improved ORR provides tangible proof that the drug is working.

58. The Duration of Response ("DoR") endpoint is the length of time that a tumor continues to response to treatment without the cancel growing or spreading. Improved DoR

demonstrates that a cancer drug can produce a durable, meaningful delay in the disease progression, as opposed to a temporary response without any lasting benefit.

59. Finally, the Disease Control Rate ("DCR") endpoint is the percentage of patients with advanced or mestatic cancer who have achieved complete response, partial response and stable disease to a therapeutic intervention in clinical trials of anticancer agents.

60. While the standard path to FDA approval of a drug or treatment can take 12-15 years, the Accelerated Approval Program dramatically shortens this timeframe: by drugs or treatments to be sold on the market after Phase 2 trials:



61. Under the Accelerated Approval Program, companies seeking approval of a drug or treatment ("sponsors"), among other things, (i) must meet the statutory standard for effectiveness—substantial evidence based on adequate and well-controlled clinical investigations; (ii) must meet the statutory standard for safety—having sufficient information to determine that the drug is safe for use under the conditions prescribed, recommended, or suggested in the

proposed labeling; and (iii) should include adequate evidence that a proposed surrogate endpoint or an intermediate clinical endpoint is reasonably likely to predict the intended clinical benefit of a drug.

62. If the FDA grants Accelerated Approval, sponsors must then conduct confirmatory trials (*i.e.*, Phase 3 trials) to verify and describe the effect on "irreversible morbidity or mortality" ("IMM"). If those confirmatory trials, however, do not confirm the predicted effect on IMM (or another clinical benefit), other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use, or the sponsor disseminates false or misleading promotional materials, the FDA can immediately withdraw the drug or treatment from the market.

63. In the run-up to the Class Period, the FDA had been burned repeatedly by granting preliminary approval of oncology drugs that it subsequently had to withdraw because they failed to provide the necessary clinical benefit—improvements in overall survival or quality of life.[7] Indeed, a recent study found that between 2013 and 2023, the FDA granted accelerated approval for 129 oncology drugs or treatments.[8] There have been 46 approvals for which at least 5 years of follow-up data were available for the study and of those 46 approvals, 22% were withdrawn because they did not provide a clinical benefit improvements in overall survival or quality of life.[9] One such case where an accelerated approval was withdrawn was Opdivo which was granted accelerated approval in 2018 for the treatment of patients with small cell lung cancer but after its

[7] Meahjabeen Hoque, Most Cancer Drugs Granted Accelerated Approval Don't Confer a Clinical Benefit, https://www.gastroenterologyadvisor.com/news/most-cancer-drugs-granted-accelerated-approval-dont-confer-a-clinical-benefit/ (April 30, 2024).

[8] *Id.*

[9] *Id.*

confirmatory studies in different treatment settings did not meet their primary endpoints of overall survival withdrew its accelerated approval in December 2020 after consultation with the FDA.[10]

C. Defendants' Pursuit of Accelerated Approval for BOT/BAL

64. Defendant Armen founded the Company in 1994 as Antigenics L.L.C. Antigenics L.L.C. was converted to Antigenics Inc. in February 2000, when the Company went public in an IPO, and on January 6, 2011, changed was renamed Agenus.

65. Agenus is a clinical-stage biotechnology company that discovers and develops immunotherapy cancer treatments, or immuno-oncology ("I-O") products in the U.S. and internationally. The Company had been developing "balstilimab," a PD-1 checkpoint blocker to treat second line cervical cancer; and "botensilimab," a CTLA-4 checkpoint blocker for the treatment of pancreatic cancer and melanoma. According to the Company, its strategy "revolves around pioneering optimal combination treatments for cancer patients, with botensilimab as [its] cornerstone."

66. Prior to the Class Period Defendants had been keenly focused on the development of balstilimab for ovarian cancer and the drug appeared to be "on its way to FDA approval."[11] On October 21, 2021, the FDA forced Agenus to "voluntarily" withdraw its Biologics License

[10] Bristol Meyers Squibb Statement on Opdivo (nivolumab) Small Cell Lung Cancer U.S. Indication, https://news.bms.com/news/details/2020/Bristol-Myers-Squibb-Statement-on-Opdivo-nivolumab-Small-Cell-Lung-Cancer-US-Indication/default.aspx#:~:text=In%20consultation%20with%20the%20FDA,a%20broader%20industry%2Dwide%20evaluation (December 29, 2020).

[11] Annalee Armstrong, *UPDATE: Agenus withdraws cervical cancer application, and a behind the scenes David vs. Big Pharma regulatory battle is revealed*, Fierce Biotech, Oct. 22, 2021, https://www.fiercebiotech.com/biotech/agenus-withdraws-cervical-cancer-application-for-balstilimab-after-fda-fully-authorizes.

Application ("BLA") for balstilimab after the agency granted full approval to a drug created by Agenus's competitor, Merck.[12]

67. Defendants were furious. The BLA Withdrawal Release emphasized that the FDA had granted full approval to Merck ***four months earlier than the FDA's goal date*** even though and "Agenus successfully completed 3 FDA inspections with no cited issues, concerns, or Form-483s." The release emphasized the clinical trial results balstilimab as compared to Merck's drug, stating that "Balstilimab achieved trial endpoints with 20% response rates in PD-L1 positive patients, versus 14% reported in pembrolizumab's label."

68. The BLA Withdrawal Release indicated that Defendants were determined not to get beaten to the punch again and stated that Agenus would "continue to accelerate development of AGEN1181 in combination with balstilimab in trials designed to rapidly support full or accelerated approval in multiple tumor types."

69. Defendants' extreme frustration with the FDA's decision quickly boiled over, and Defendant Armen made a series of public statements excoriating the FDA. In an October 18, 2021 letter sent to Richard Pazdur, head of the FDA's oncology center of excellence, Defendant Armen wrote, "This seemingly-quick approval of [Merck's drug] pembrolizumab hours before Agenus's LCM [late-cycle meeting] suggests that FDA may have afforded special consideration to Merck, the sponsor of the pembrolizumab application." Defendant Armen continued, "[t]he fact that pembrolizumab's approval blocked Agenus's chances of accelerated approval further implies that FDA was not intending to afford balstilimab the full and fair review that it deserves." The letter asked Pazdur to step in to ensure the FDA is fostering an environment that supports innovation and competition to "offset a monopolistic environment by large companies."

[12] *Id.*

70. And Defendant Armen did not stop there. During an interview following a conference call with investors on October 22, 2021, Defendant Armen said, "The first thing [the FDA] did was cite the fact that Merck had been approved, and the window for us for accelerated approval was no longer available" and "[the FDA] didn't discuss any substance, nothing about the product efficacy or anything like that. So as far as we're concerned, this is a technicality and the agency's entitled to do whatever they need to do."

71. Having lost the race to gain balstilimab approval, Defendants turned to developing an immunotherapy for the treatment of cancer, including MSS CRC, that combined Agenus's botensilimab and balstilimab checkpoint blockers ("BOT/BAL").

72. Already burned by the FDA's approval of pembrolizumab over balstilimab, Defendants knew that they had to obtain Accelerated Approval for BOT/BAL because investors would fear that the Company would be beaten to the punch again. In addition, Accelerated Approval of BOT/BAL was essential to Agenus's bottom line. Prior to and during the Class Period, the Company was hemorrhaging money. For example, while the Company reported cash and cash equivalents of $307 million as of December 31, 2021, that balance has fallen 37% to $193 million by December 31, 2022. By December 31, 2023, Agenus's cash had fallen another 60% to $76 million. Desperate for financing as its cash dwindled, the Company sold $84.4 million in shares in 2023, including sales of $20.3 million in Q2 2023, and $24.4 million in shares in the period of January 1, 2024 through March 8, 2024, for total net proceeds totaling $149.8 million.

73. Throughout the Class Period, Defendants repeatedly (and misleadingly) touted to investors that Agenus could obtain Accelerated Approval from the FDA for BOT/BAL because the treatment's clinical trials were tailored to the FDA's Accelerated Approval criteria, trial data was demonstrating the durability and overall survival endpoints that were critical to the FDA's

decision-making, and the Company's internal processes, technology, and expertise were designed to facilitate Accelerated Approval.

74. For example, on January 23, 2023, Agenus issued a press release during pre-market hours "announc[ing] clinical data from the MSS CRC (microsatellite stable colorectal cancer) 70 patient cohort of a Phase 1b study of botensilimab (multifunctional Fc-enhanced anti-CTLA-4) in combination with balstilimab (anti-PD-1) in patients with chemotherapy and/or immunotherapy-resistant tumors." The press release quoted Defendant O'Day as stating: "This data highlight the ***deep and durable responses*** achieved with botensilimab and balstilimab in advanced MSS CRC, underscoring remarkable benefit for these patients who have failed standard of care or other investigative therapies." Similarly, recognizing the need to assure investors that Agenus had the expertise and organizational prowess to obtain Accelerated Approval, Defendants consistently represented in SEC filings during the Class Period that:

> In addition to a diverse pipeline, we have assembled fully integrated end-to-end capabilities including novel target discovery, antibody generation, cell line development and current good manufacturing practice ("cGMP") clinical manufacturing. ***We believe that these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard***.

75. On April 17, 2023, Defendants received some good news. The grant Agenus a "Fast Track Designation" for BOT/BAL for patients with non-MSI-H/ dMMR (*i.e.*, MSS tumors) metastatic CRC with no active liver involvement, and who had been "heavily pretreated [and] are resistant or intolerant to a fluoropyrimidine, oxaliplatin, and irinotecan, and who have also received a VEGF inhibitor, an EGFR inhibitor and/or a BRAF inhibitor, if indicated."

76. Defendants were ecstatic. In the press release announcing the news, Defendant O'Day touted that "The Fast Track designation offers important benefits, including the potential eligibility for a Priority Review, and ***we will be working with the FDA and all key stakeholders***

to rapidly advance the botensilimab/balstilimab combination in colorectal cancer as well as other solid tumor indications." After receiving the Fast Track Designation, Defendants quickly announced the creation of a global, randomized Phase 2 trial and stated that it expected a global Phase 3 trial was expected to commence in 2023.

77. After the Fast Track announcement, Defendants' touts regarding BOT/BAL and its potential Accelerated Approval shifted into overdrive. On June 30, 2023, Agenus shared new data from its Phase 1b trial of BOT/BAL. Defendants issued a press release entitled "ESMO GI Data: Agenus' Botensilimab/Balstilimab Combination Achieves ***Unprecedented Survival*** in Advanced Colorectal Cancer." The press release touted that the clinical trial data ***"show substantial survival benefits and long-lasting responses*** for patients with non-MSI-H (microsatellite stable or non-microsatellite instability-high) metastatic colorectal cancer previously resistant to chemotherapy and/or immunotherapy" and "demonstrate ***remarkable median overall survival and sustained responses*** in heavily pre-treated patients that historically haven't responded to immunotherapy."

78. With the Company hemorrhaging money, Defendants officially went all-in on BOT/BAL. On August 23, 2023 Agenus announced it would temporarily postpone all other preclinical and clinical programs and lay off 25% of its workforce to cut costs and focus on commercializing BOT/BAL. According to Defendants, by focusing on BOT/BAL, Agenus "expect[ed] to expedite regulatory approval."

79. Carrying on with its plans to focus exclusively on the BOT/BAL program, on October 10, 2023 Agenus announced it completed enrollment in its randomized Phase 2 clinical trial of BOT/BAL in advanced CRC. Despite this announcement, at least two test subjects were not fully onboarded until at November, which meant that even six-month Phase 2 trial data would

not be available to present to the FDA for these patients if Defendants presented data to the FDA in July 2024.

80. Undaunted, on November 7, 2023, Defendants held a call with analysts and investors to review the Company's performance in the third quarter of 2023 ("Q3 2023 Call"). During the scripted portion of the call, Defendant Armen touted that "***the positive trends and lasting responses in our studies strengthen our conviction in BOT/BAL potential. Our top priority is obtaining BOT/BAL approval in MSS-CRC*** in order to allow patients access to this important IO treatment, ***offering them new hope***, which does not exist today."

81. Defendant Armen's statements, however, referred to Phase 1 trial data, not Phase 2. Recognizing that any presentation to the FDA concerning Accelerated Approval would also need Phase 2 data, later in the Q3 2023 Call, analyst Emily Bodnar of H.C. Wainwright asked, "when we may expect to see initial Phase II data for the MSS CRC study?" Defendant Armen responded by assuring attendees about the strength of Agenus's Phase 2 studies:

> But -- so what I've said publicly is the fact that we have clearly disclosed the data on the first 70 patients, ***not because the rest of the data isn't satisfactory, but the rest of the data needs to be cleaned up and we need a little bit of work to do. But our look at the data both in the second call and in our Phase II studies indicate that we should have a sustainable response rate, perhaps even an improving response rate as we disclose and analyze these data for regulatory and beyond purposes***. So that is going to be more of a regulatory decision, when to disclose it and the ideal circumstance for us will be certainly to publish the data at around the time of a potential BLA submission. To publish the data in the journal that would be part of our plan.

82. After that exchange, analyst Colleen Kusy from R.W. Baird followed up about the data Defendants planned to present to the FDA in connection with Accelerated Approval should they receive the opportunity. Kusy asked, "And at the time of BLA submission [for BOT/BAL for MSS CRC], would you expect to have any sort of overall survival early data from this [Phase 2] study?" Defendant Yancey, Agenus's SGDA, responded, "***So I certainly expect that we'd be able***

to demonstrate a point estimates for response, durability of response for patients with stable disease or better and that is trending toward a survival benefit . . . . I think we have a very, very robust set of data to present to the agencies for their review."

83. Still later on the Q3 2023 Call, in response to a question from B. Riley analyst Mayank Mamtani, Defendant Armen emphasized that Agenus had the ability to demonstrate a sufficient survival benefit for preliminary approval of BOT/BAL for MSS CRC, stating in no uncertain terms that "of course, ***there are regulatory and other questions about do overall response rates translate to longer-term benefit. We know they do. We need to demonstrate that with numbers, but with CTLA-4 binding antibodies and ours is a multifunctional broad functioning molecule that binds the CTLA-4 as one of its five different activities, not just the center stage activity, but one of five different activities***."

84. Defendants continued to tout BOT/BAL in 2024. On March 14, 2024, Defendants held a call with analysts and investors to discuss Agenus's fourth quarter and full year 2023 performance (the "2023 Call"). Clearly leery about Defendants' confidence going into their meeting with the FDA (which had yet to be scheduled), Matthew Phipps, an analyst with William Blair, asked Defendant Armen directly, "Garo, ***why not disclose at least some indication of the top line results, I guess, in May, given the six months follow-up by that point? Why wait till after you meet with the FDA to at least, I guess, say whether or not or endpoint has been met or something like that?***" Defendant Armen flatly refused to provide any information on data in advance of the meeting, stating "It's strictly regulatory courtesy. I think it would be not appropriate if we're ready to present that data to the FDA to make that public right before our FDA meeting."

85. But questions about the adequacy of Defendants' data did not go away. On May 7, 2024, Defendants held a call with analysts and investors to discuss Agenus's first quarter 2024

performance (the "Q1 2024 Call"). On the call, analyst Emily Bodnar of H.C. Wainwright asked, "could you confirm how many patients you've treated with BOT/BAL at the recommended Phase 2 dose across the Phase 1b and Phase 2 studies specifically for MS CRC patients without? And your confidence, I guess, that you have enough efficacy data to support an accelerated approval?" Defendant O'Day refused to answer the question, but made sure to create the impression that the data was sufficient for Accelerated Approval, telling attendees that, "***we're not going to get into the absolute specific numbers*** but we can -- what I can say is ***with the Phase 1 and the Phase 2 trial, we have 2 active doses and a significant number of patients on the combination of BOT/BAL in both the Phase 1 and the Phase 2 randomized trial that we think are supported with safety, efficacy and clinical pharmacology to discuss with an accelerated pathway*** given the unmet need in this setting."

86. Analysts on the Q1 2024 Call would not relent, however. Mayank Mamtani of B. Riley Securities immediately followed up, asking, "in prior press release team, you've mentioned that your emerging data in Phase 2 is encouraging. And today, I think you said it's comparable to what you noted in Phase 1 at a similar stage. Are you able to give a little bit more detail on what parameters we are talking about and it's comparable to your expectation at the outset and especially given you're enrolling slightly earlier stage patients there? And then secondly, on the -- if you are able to clarify the FDA meeting has been scheduled. And if there's a minimum follow-up from the Phase 2 cohort that you're trying to accomplish before you're able to submit a package that would go alongside that everything."

87. Defendant Armen responded sharply, stating, "***Mayank, we have said repeatedly, that we will not discuss the details of this study and please understand everybody that we're not trying to be cute here, it is just a courtesy call that we will not discuss the data and ensure we***

have an opportunity to present it to the FDA. And subsequent to that, our preference is, of course, to present the data which we consider a very important set of data that will address the selection of the dose, contribution of the elements and the efficacy to support the data that we have seen in earlier trials and a major. That would be our preference to do it. So you will get no further details on this until these steps are underway."

88. The analyst did not back down, however, and asked, "On the follow-up from the Phase 2, like you are at, I think, 14 months follow-up in the -- from the Phase 1. ***Is there a particular requirement or best practices in terms of how much follow-up you need to have from Phase 2?*** Or is that sort of subject to discussion?" Defendant Armen responded by falsely assuring analysts and investors that their data was sufficient with regard to Phase 2: "the FDA has guidance that is based on historical precedents on the minimum follow. But we have had significant input from our regulatory advisers on what that minimum should be. Of course, ideally, we can wait 5 years but we're not going to do that. ***But the minimum enrollment in the Phase 2 ended in October 2023. And based on that, you can sort of extrapolate what the follow-up period will be between now and the potential FDA meeting***."

89. On May 16, 2024, Defendants announced that they would be getting the chance to present BOT/BAT data to the FDA at an "end of Phase 2" meeting ("EOP2 meeting") in July, two months later. At the meeting Defendants would present the Phase 1 and Phase 2 data they had touted to investors to gauge the agency's interest in Accelerated Approval of the BOT/BAL. Defendants issued a press release entitled "FDA Grants Agenus Type B End-of-Phase 2 Meeting to Discuss BOT/BAL Therapy for Relapsed or Refractory Metastatic Colorectal Cancer," which quoted Defendant O'Day touting that

> Our upcoming End of Phase 2 meeting with the FDA represents a significant milestone in the ongoing development of BOT/BAL for patients diagnosed with

> metastatic MSS CRC who do not have active liver metastases . . . . ***The results from our Phase 1 and Phase 2 studies contribute valuable insights into the potential of this therapy for managing a specific and challenging subgroup of colorectal cancer***. We remain dedicated to further exploring innovative immunotherapeutic strategies.

90. Defendants statements throughout the Class Period had created in the impression in investors that Agenus could obtain Accelerated Approval from the FDA for BOT/BAL because the treatment's clinical trials were tailored to the FDA's Accelerated Approval criteria, trial data was demonstrating the durability and overall survival endpoints that were critical to the FDA's decision-making, and the Company's internal processes, technology, and expertise were designed to facilitate accelerated approval.

91. Unfortunately, while Agenus employees knew the truth about the Company, BOT/BAL, and the available data for the EOP2 meeting, investors had no idea that they had been misled.

D. Defendants Repeatedly Misrepresented the Likelihood of Accelerated Approval, the BOT/BAL Combination Treatment, and Agenus's Capabilities Throughout the Class Period

92. According to multiple CWs, unbeknownst to investors, despite Defendants' touts, the Company lacked the data necessary to obtain Accelerated Approval of BOT/BAL for the specific types of CRC the FDA had fast-tracked, and Defendants knew it. The CWs also described how Defendants intentional or recklessly misrepresented the BOT/BAL treatment over the objections of multiple Agenus executives, who were fired or laid off after pushing back. Finally, statements by CWs demonstrate that the Company never had any ability to accelerate the development of its treatment candidates because Defendant Armen insisted on development plans unsupported by data and made up out of whole cloth; fired, laid off, or pushed into resigning so many employees that the Company was not adequately staffed; and consistently refused to pay

vendors, which caused supply shortages and manufacturing shutdowns even as Defendants prepared to seek Accelerated Approval of BOT/BAL.

1. Defendants Knew that Agenus Lacked Sufficient Data for Accelerated Approval

93. Defendants knew that the FDA would not grant Accelerated Approval for BOT/BAL unless Agenus provided substantial, reliable evidence of durability and overall survival rate. According to multiple CWs, however, Agenus's Phase 1 and Phase 2 tests for MSS CRC lacked this evidence and were doomed to fail, and Defendants knew it. In fact, when confronted with this, Defendant Armen retorted "who cares about FDA, they can't stop us" and "we're going to submit with what we have because this is a breakthrough and they should not deny it."

94. According to CW6, the Agenus employees in charge of BOT/BAL clinical trials and studies were Defendant O'Day, Grossman, Agenus's then-Senior Medical Director of Clinical Development, and Patel, Agenus's Executive Medical Director/Head of Biomarkers and later Agenus's Vice President of Translational Research. CW6 stated that Defendant O'Day, Grossman, and Patel got "the final numbers" on the studies, spoke regularly about the regulatory process and were "constantly looking at data." As to Defendant Armen, CW9 stated that in November 2021 he and then Senior Director of Data Science Kris Brown ("Brown") developed the "Interactive Patient Tracker" a dashboard for Defendant Armen to enable him to review anonymized clinical data in a more approachable way. According to CW9, Defendant Armen began using the Interactive Patient Tracker in November or December 2021 and continued to use it when CW9 left Agenus.

95. Despite this close attention, however, Defendants' efforts to obtain Accelerated Approval were doomed virtually from the start. In November 2022, for example, VP of Biostatistics and Data Management James Song ("Song") told CW6 that the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data.

96. CW6 further described how David Savitsky, an Agenus director in pre-clinical development ("Savitsky"), and CW6's counterpart in the preclinical arm of the Company, helped create BOT/BAL. According to CW6, Savitsky sent him texts in 2022 and 2023 expressing frustration with how the regulatory process for BOT/BAL was being managed, including telling CW6 that the Company was "trashing my drug" and that he was sure the FDA would reject the molecule. CW6 further said that Savitsky was concerned that the Company was moving too fast with its trials and that upper-level management at Agenus was inexperienced and continued to make decisions that would squander BOT/BAL's chances of making it to the market. Defendants refused to acknowledge Savitsky's concerns; CW6 stated that in March 2023, Savitsky was excluded from any discussion or work related to BOT/BAL.

97. Savitsky's concerns, however, proved prophetic. CW6 described regularly attending a weekly safety meeting led by Katherine Rosenthal ("Rosenthal"), Agenus's Director Clinical Program Management from May 2021 through November 2023. This virtual video meeting was to discuss all of Agenus's active studies and any safety signals that might need to be escalated to Defendant O'Day. The meeting included Agenus clinical scientists, medical monitors and other lower ranking executives in clinical development.

98. At a weekly safety meeting in spring 2023, the group discussed how to wind down Phase 2 trials and ramp up a Phase 3 study. At this meeting, CW6 stated that Grossman updated the group on the Company's plans. CW6 stated that Colburn, Agenus's then-VP of Clinical Science, who reported to Defendant O'Day until she was fired or laid off in May 2023, confronted Grossman, stating, "the FDA doesn't do that. It's not going to happen. You can't do it that way." CW6 said it was the first time he had heard Colburn speak up so strongly in a meeting and that Grossman fell silent and did not respond. CW4, who also attended the safety meetings, but did not

attend this one, corroborated that Colburn had confronted Grossman and said he had heard about the confrontation from a colleague. CW6 said that he believed that Colburn expressed her feeling directly to Defendant Armen as well, and that Grossman was responsible for reporting the meeting results, including comments like Colburn's, to Defendant O'Day.

99. According to CW3, who worked on BOT/BAL through December 2024, months past the EOP2 meeting, Defendants' data on BOT/BAL was not mature enough to bring to the FDA because Agenus had only completed Phase 1 trials and was early in Phase 2 trials, and thus the data regarding survival and durability was not robust, specific, or sufficient to obtain Accelerated Approval. Among other things, CW3 said, Phase 1 drug trials do not include enough patients to make any affirmative statements about a new therapy, and only show signals about a drug. In addition, while Phase 2 data provides more efficacy insight and uses a broader set of patients, Phase 2 data does not provide any declarative insights into survivability rates. This makes it difficult to develop a "good sense" of how effective an immunotherapy treatment might be based solely on Phase 1 and early Phase 2 results. This was especially so for participants in BOT/BAL studies, who were "heavily pre-treated with a lot of different things including patients who had already done immunotherapy," and thus it is difficult to pinpoint whether any positive response is a result of BOT/BAL or something else.

100. This was why, CW3 said, Phase 3 trials are so important: they include a much larger group of patients, and thus only at that stage can one draw definitive conclusions about objective response and survival rates. Accordingly, as studies become larger, objective response rates decline because of the larger trial cohort. This was why, CW3 said, "to my knowledge, [survival] wasn't something we spoke about in the field. We never said, 'This is going to offer increased survival.'" In addition, CW3 said that it was not appropriate to describe BOT/BAL as providing

"unprecedented responses" in treatment. To CW3, "we needed the data to say a lot more than 'It's exciting and there is potential,'" and this was why it was too early to go to the FDA.

101. CW3 stated that he raised the issue about Agenus's BOT/BAL data directly to his manager, Agenus's Vice President of Medical Affairs, in May-June 2024, and that this view was shared by several Medical Liaisons in Agenus's Medical Affairs department, who did not understand why the Company was moving forward with submitting BOT/BAL for Advanced Approval. In fact, CW3 stated that these concerns were raised and discussed in a meeting with the team of Medical Liaisons. CW3 further stated that it was "impossible" for Agenus's executives not to know about "the gaps" in the BOT/BAL research data, because "[t]hey had to know . . . they just did," given that Agenus's executives are responsible for speaking with FDA representatives and knew non-public clinical data for BOT/BAL.

102. CW7 stated that Agenus's own FDA Submission Team shared CW3's view. According to CW7, the Company's FDA submission team had advised Defendant Armen against aggressively pursuing FDA approval, saying that the Company needed more time on trials. "Everyone was saying we need more time," CW7 said. CW7 said other executives repeatedly confronted Defendant Armen with the fact that the data available regarding BOT/BAL was so small that the company simply could not submit such small numbers to the FDA and expect to obtain Accelerated Approval. CW7 said that in these conversations, Defendant Armen responded, "every patient counts," "who cares about FDA, they can't stop us" and "we're going to submit with what we have because this is a breakthrough and they should not deny it." Indeed, according to CW4 Agenus was "overconfident about how FDA was reviewing data" to the point "it was almost delusional."

2. Defendants Intentionally or Recklessly Misrepresented BOT/BAL's Efficacy

103. Defendants were repeatedly warned by Agenus executives not to misleadingly tout the efficacy of BOT/BAL, but nevertheless ignored this advice. CW9 stated that Defendant Armen's glowing language about BOT/BAL lacked substantial clinical evidence, and that Defendant Armen's confidence in the drug was based on one or two patients in 2022 showing a strong response to the treatment. CW9 further stated that the Company's data scient team and IT team, which CW9 led, attempted to take the emotion out of analyzing BOT/BAL and instead focus on facts, but were laid off or resigned, including then Senior Director of Data Science Kris Brown ("Brown").

104. CW4 stated that Defendant Armen's statements to investors appeared "over the top," including about the impact BOT/BAL could have on cancer treatments. CW4 also heard that others had asked CEO Armen to "tone down" his language around the drug because it was not strictly scientific.

105. CW7 also described how Defendant Armen making misleading public statements about BOT/BAL. CW7 led meetings on a weekly or biweekly basis to discuss key updates on the Company's studies and clinical trials for BOT/BAL, which included Agenus's Corporate Communications Officer and Abrams, the Company's Chief Counsel. In these meetings, and in one-one discussions directly with Defendant Armen, CW7 insisted that Agenus be careful about how they talked about BOT/BAL, specifically by ensuring that the Company share only accurate, balanced, and scientifically supported information about the treatment. CW7 said Defendant Armen ignored this feedback. When CW7 spoke to Defendant Armen, Defendant Armen often said, "we save lives," which CW7 found patently misleading because some clinical trial patients relapsed after BOT/BAL treatments. In other words, "it wasn't like the cancer went away." CW7 said, however, that was not the message Defendant Armen wanted to present. CW7 said that

Defendant Armen, "didn't understand the field." CW7 further stated that the Company's claims of "unprecedented survival" were improper, because while some patients with tumors showed longer survival benefits, the numbers were small, inconsistent and didn't meet statistical limitations.

106. Not only did Defendant Armen insist on misrepresenting BOT/BAL's efficacy, he also repeatedly removed any obstacles to his making such statements by firing or laying off any executives who disagreed with him. For example, CW4 described how Defendant Armen would fire or lay off high-ranking employees at Agenus who raised concerns about BOT/BAL's drug trials. CW4 stated that these executives included former Chief Business Officer Julie Desander ("DeSander"), former Chief Legal Officer Robin Abrams ("Abrams"), and former Chief Communications Officer Stephanie Fagan ("Fagan"). Desander and Abrams were both let go or fired in March 2024, and Fagan was let go or fired in spring 2024 prior to the EOP2 meeting as well.

107. CW7 corroborated CW4's account. CW7 stated that Abrams insisted on hiring a Compliance Officer and told Defendant Armen that he could not use sales language to describe BOT/BAL. In addition, Agenus's then-Chief of Patient Advocacy confronted Defendant Armen about this as well. CW7 stated that both Abrams and the Chief of Patient Advocacy were then either fired or let go. CW7 further stated that Fagan was also laid off or fired because she disagreed with Defendant Armen's approach. CW7 said that "it was like hell for [Fagan]," CW7 confirmed that DeSander was also laid off after disagreeing with Defendant Armen as well.

108. CW8 corroborated CW4 and CW7's accounts as well. CW8 described Agenus as a "poorly run organization" where Defendant Garmen "didn't listen to management team and when you disagreed with him you were let go. Then rinse and repeat."

3. Agenus Lacked the Capacity to Accelerate the Treatment Development Process

109. Statements from CWs also make clear that Agenus did not have "fully integrated, end-to-end capabilities" that will "uniquely position us to produce novel therapies on accelerated timelines," clinical programs "designed to support regulatory pathways for accelerated development." Instead, according to CW8, Defendant Armen came up "with his own ridiculous plans that didn't make sense and weren't grounded in reality." CW8 described how Defendant Armen continuously added new indications to BOT/BAL Phase 1 trials without consulting or heeding the advice of the medical team and pressured his employees to do this even if it put the Phase 1 trial out of compliance.

110. CW6 also described seeing new indications being added to BOT/BAL Phase 1 studies without any rhyme or reason. CW6 stated that during the above-described weekly safety meetings he attended that were led by Rosenthal, there were discussions of adding as many patients as possible to Phase 1 studies of BOT/BAL, and it appeared to CW6 that Agenus was rushing to add patients as quickly as possible. CW6 said that the speed with which Agenus was trying to conduct these trials was creating logistical issues. For example, CW6 recalled multiple vendors sending samples to the wrong places because of accountability and communications issues.

111. According to CW6, Defendant Armen's desire to add as many indications as possible to Phase 1 trials did not position the Company on any accelerated timeline. Rather, it had exactly the opposite effect. CW6 stated that adding additional indicators can dilute or obscure the trial results and recalled that a consultant told Agenus's FDA Submission Team that the FDA would only accept data concerning four or so indicators.

112. CW8 described how the Company's attempt to fulfill Defendant Armen's arbitrary desire to accelerate Phase 2 clinical trials for BOT/BAL was an utter failure. CW8 stated that when a company is developing projections completing patient enrollment, it looks at similar previous

studies to come up with a data-driven timeline. Based on these factors, CW8 estimated that patient enrollment would be completed by September 30 of 2023 for the Phase 2 colorectal study of BOT/BAL in support of the treatment's Accelerated Approval application. Defendant Armen flatly rejected this timeline and insisted it be done in 6 months, but provided no evidence indicating that this could be accomplished. Rather than listen to CW8, Armen laid him off in May 2023, and replaced him with a new team. CW8 learned that within months, that new team was replaced by yet another new team. Indeed, CW6 corroborated that CW8 was laid off and replaced by a vendor, which was replaced by a second vendor within months. According to CW8, the Company kept missing Defendant Armen's new Phase 2 timeline and patient enrollment was not completed until October 15, 2023, *i.e.*, what CW8 originally projected.

113. Defendant Armen's consistent hostility to the FDA, reflected in his comment, "who cares about FDA, they can't stop us," also prevented the Company from attaining any acceleration in its treatment efforts. According to CW4, Defendant Armen was "antagonistic" to the FDA, particularly in light of his comments about the FDA after Agenus withdrew its application for Accelerated Approval of balstilimab for cervical cancer in 2021. CW8 corroborated this, stating that while the FDA's regulations and guidelines are what is supposed to drive any pharmaceutical company's strategy for drug approval, under Defendant Armen that was not Agenus operated. Indeed, CW9 described how Armen's animosity toward the regulatory agency was notorious. According to CW9, Armen was constantly making comments about how the FDA is corrupt. Armen believed that the FDA only impeded drug development and held it responsible for Agenus' drug failures. In fact, prior to the Class Period, in March 2022, Defendant Armen directed CW9 and former Executive Director of Data Engineering James Roberts to write a white paper outlining how a company could achieve drug approval without involving the FDA.

114. CW8 also described how Defendant Armen's irrationality and temperament directly led to high attrition at the Company, which further precluded it from pursuing any accelerated timelines. For example, when CW8 joined Agenus, he met with the resigning Clinical Operations head Randy Hurley ("Hurley"). Hurley presented an organizational chart to CW8 that had a number of unfilled positions and explained that the roles should be filled, but so many people had resigned that Agenus was unable to fill them.

115. CW2 corroborated that the constant staff turnover and layoffs made difficult for the Company to operate. He said the work environment was "disruptive" with a number of layoffs and people leaving voluntarily. According to CW2, Agenus was desperate to shorten the timeline for BOT/BAL development to impress investors, not because the Company had the ability to do so. Indeed, when CW2 began working as an Agenus contractor, his first task was to process six to seven months of backlogged documents that had accumulated after a prior clinical associate had left, in addition maintaining documentation of current trials. CW2 felt pressure to complete all this work in impossibly shortened timeframes, and later learned in May/June 2023 from conversations over the chat tool Slack with his manager, Paul, and/or an Agenus clinical scientist that the pressure to shorten the timeframe for BOT/BAL development was coming from Agenus's Medical Affairs team. Paul also told him via Slack that the reason for the pressure was that the Company was desperate to obtain data that it could use to impress investors and augment the data it planned to submit to the FDA in early 2024. Despite lacking sufficient staff, CW2 said that Agenus continued to add patients to Phase 1 testing cohorts to test various combinations of cancers and immunotherapy drugs, which led to a massive enrollment in Phase 1 tests of 200 to 300 patients in only a matter of months, which was incredibly rushed. CW2 estimated that Agenus was

processing an astonishing 8-10 enrollment packets a week for Phase 1 trials and accepting 90% of candidates.

116. Agenus also lacked the ability to operate on any accelerated timeframes because of supply shortages caused in part by Defendant Armen's refusal to pay vendors. For example, CW9 stated that Agenus was notoriously late in paying vendors for services. In fact, the day he was hired, he chatted with the then-Chief Legal Counsel who told CW9 that "everything was a mess" because the company wasn't paying any bills. CW9 himself inherited two signed contracts and was instructed by Defendant Armen directly to not pay them. One contract was a three-year agreement with Clarivate, a business intelligence firm, for access to its gene database. A year into the contract, CW9 said, Defendant Armen instructed him not to pay Clarivate any longer. The second contract was with Katana Labs, a startup which offers an advanced cloud- and AI-based image analysis pipeline in cancer diagnostics. Agenus worked with Katana to build knowledge graphs for immune blocking therapies, and Katana Labs hit every milestone detailed in the $350,000 contract. But Defendant Armen refused to pay them. CW9 also recalled a conversation with Defendant Armen in 2022 where Defendant Armen said that investor interest in biotech companies was low so "we need to get the stock price up," and added that he (*i.e.*, Defendant Armen) needed to come up with funding or ways to not pay people.

117. CW1 described biweekly and monthly meetings regarding quality assurance meetings concerning the BOT/BAL combination therapy. CW1 attended meetings in September 2023 and March 2024. The meetings were led by Agenus Chief Quality Officer Humes and/or CW1's supervisor, Zahora, and were attended by Krishnaveni Gottam, the Company's good manufacturing practices ("GMP") quality assurance operations site head, who worked at Headquarters. The meetings were to "get everyone on the same page" regarding quality assurance

with the combination therapy and organize the quality assurance team to make sure they were staying on track for the ensuing month and preparing for future tasks related to clinical trials.

118. CW1 recalled that the meetings discussed manufacturing issues resulting from problems obtaining necessary supplies from "donors" and vendors. CW1 described "donors" as clinical trial subjects who agreed to participate in the study and donated blood to receive personalized BOT/BAL combination immunotherapy treatment. According to CW1, Agenus took the donor blood, mixed it with the combination therapy of botensilimab and balstilimab and then administered it to the donor. Vendors included a number of companies who manufacture supplies such as latex gloves, vials, cassettes and other item needed for the drug manufacturing process.

119. CW6 also described shortages connected to BOT/BAL's development. In May 2023, CW6 was told by Agenus project manager Linh Mach ("Mach") at a check-in meeting that Agenus was heading toward a drug shortage problem and that Phase 3 trials of BOT/BAL were not going to happen because botensilimab takes a year and eight months to manufacture, and the timeline for submission to the FDA was a year. CW6 told Mach to report this information to the Agenus's Chemistry, Manufacturing, and Controls Department ("CMC").

120. CW1 further recalled that on or about March 11, 2024, Gottam pulled him and Sara Ashworth King, a Manager, Quality Assurance Doc Control at Agenus ("King"), with whom CW1 was working at the time, at Agenus aside to give them a "heads-up" that the Company was having issues receiving orders of donor blood and supplies from vendors because the Company was behind on payments. Gottam told CW1 and King that she had been in multiple meetings with Agenus directors where the discussed concerns about the failure to pay vendors and ensuing supply issues. CW1 stated that Agenus had had to halt manufacturing concerning clinical trials because of the donor and supplier issues, and that he was left with "nothing to do" because of the stoppage.

121. Like CW1, CW3 also described how vendors refused to work with Agenus because they were not paid. Specifically, CW3 recalled that during his time at Agenus, multiple clinical research organizations and investigator sponsor trial vendors refused to continue to work on anything related to BOT/BAL because they had not been paid. CW4 also described hearing about that vendors were not being paid during his time at Agenus as well.

E. Investors Learn the Truth as the Concealed Risk of BOT/BAL Failing to Obtain Accelerated Approval Emerges

122. During the Class Period, Defendants' misstatements kept in the dark about the extent of the risk that BOT/BAL would not receive Accelerated Approval, the fact that the Phase 1 and Phase 2 clinical trial data did not support Defendants' rosy descriptions of BOT/BAL, and Agenus's operational inability to accelerate a drug development timeline. These false statements also propped up Agenus's share price and enabled the Company to reap $144 million in much-needed capital at the expense of unsuspecting investors.

123. Accordingly, investors were stunned when Defendants statements' were revealed to be false and misleading, and the risks concealed by those statements emerged, upon the publication of the EOP2 Release on July 18, 2024. In that release, Defendants announced that the FDA had dashed any hopes of obtaining Accelerated Approval for BOT/BAL, which increased the likelihood that a competitor would obtain approval earlier (thereby ruining the drug's market potential) and that there was a strong possibility that Agenus would not have the funds to conduct Phase 3 trials.

124. The EOP2 Release also revealed a number of facts that blind-sided investors. First, interim topline data from the Phase 2 study showed that patients treated with the 75-mg dose of BOT/BAL experienced an "overall response rate" ("ORR") of 19.4%, and patients given the 150-mg dose of BOT/BAL experienced an ORR of only 8.2%, even though there was no evidence of

toxicity from the higher dose and the maximum-tolerated dose was not reached. This meant that a 150mg dose of BOT/BAL was less than half as effective as a 75mg dose, even though the larger dose did not harm the patient, which threw into serious doubt BOT/BAL's long term effectiveness. Further, the interim Phase 2 data Defendants presented to the FDA was not even complete in an interim sense, as two class members had not participated in the clinical trial long enough for the FDA to credit their data.

125. Although the FDA's statements to Defendants at the EOP2 meeting were not made public, CW5 attended the EOP2 meeting and confirmed that the FDA had found that the Phase 2 results presented at the EOP2 meeting were not strong enough, and that Agenus did not have enough data on the survival benefit of the drug. CW5 attributed this, at least in part, to the fact that the FDA had granted Accelerated Approval to a number of cancer treatments based on objective response rates in early clinical trials which ultimately were rescinded.

126. On this news, Agenus's stock price fell $10.43 per share, or 58.83%, to close at $7.30 per share on July 18, 2024.

127. This news was discussed negatively throughout the biotech community. In an article titled "FDA wrecks Agenus' accelerated approval plan, triggering push to partner cancer combination" published on the day the news came out, Fierce Biotech described the phase 2 data as "immature" and said, "Agenus had little to cheer coming out of the meeting." It added, as a result of the FDA's denial of Agenus' plans to seek accelerated approval, Agenus has been prompted into "look[ing] into partnering to fund the phase 3 required to reach the market." The news article also explained how Agenus "went all in on the combination of its CTLA-4 blocking antibody botensilimab and PD-1 candidate balstilimab to cut costs last year."

128. Further, a second article titled "Future of Agenus' Immunotherapy Combo Uncertain as FDA Discourages Accelerated Approval in CRC," BioSpace also wrote about Agenus "seeking potential alternative pathways to make BOT/BAL available to patients." The article emphasized Agenus' poor financial condition and the dire significance of it obtaining accelerated approval. It also quoted an interview by Endpoints News with Defendant Armen in the wake of the EOP2 meeting, who revealed that the Company "cannot justify, without near-term commercialization revenue coming in, funding a full-fledged Phase 3 trial that will yield commercialization in three or four years in the absence of an accelerated approval pathway."

F. Post-Class Period Events

129. On August 8, 2024, in the aftermath of the Denial Announcement, Defendants held a call to disclose Agenus's financial performance for the second quarter of 2024 ("Q2 2024 Call")., Defendant Armen's that low opinion of the FDA was readily apparent on the call, confirming multiple CWs' characterization of him. For example, in response to a question from Jefferies analyst Claire Duffy about conversations with European regulatory agencies, Defendant Armen stated, "We've had the very initial interaction with one of the major [European] agencies. And I will tell you their stance on this is diametrically opposite to the U.S. FDA, diametrically opposite. What do I mean by that? They have done their homework." Defendant Armen continued, "they understand the data, they have had slightly more mature data than what we had presented with to the FDA, because as you know, the FDA has very strict rules on not considering data post-submission of the package, and between the submission of the package and the meeting could be several months." Defendant Armen continued "[s]o even though we had more mature data by the time we had the actual meeting, this data wasn't being formally considered in their consideration of their guidance to us. But the European agency has seen this more mature data, and their guidance to us is very simple, that they have indicated several pointers that will be helpful to us in making

sure that we meet all the requirements, but they've also said to us that they hope that these requirements, which are important box-checking elements, will not get in the way of our rapid exploration of submission."

130. Astonishingly, Defendant Armen also essentially confirmed that Agenus did not have sufficient survival data for the BOT/BAL Treatment. When asked by B. Riley Financial Analyst Madison El-Saadi about "expectations on survival and durability," Armen stated, among other things, that "We are confident that in an immuno-oncology treatment setting, ***any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit***. I think this is a point that certain agencies understand, and other agencies like the FDA, I think, need to be schooled in this phenomenon." In other words, Defendants' ***had been assuming the existence of a survival benefit*** from Agenus's BOT/BAL data, Agenus did not have Phase 2 trial data demonstrating an overall survival benefit in hand when Agenus met with the FDA.

131. On November 12, 2024, Defendants held a call to disclose Agenus's financial performance for the third quarter of 2024 ("Q3 2024 Call"). During the call, H.C. Wainwright analyst Emily Bodnar asked for an update on Phase 3 clinical trials of BOT/BAL, in light of the feedback from the FDA and a European regulator. Agenus Chief Commercial Officer Robin Taylor replied that "So to address your question around the Phase 3 design and timing. We now have, as-you noted, we have feedback both from EMA and FDA that really allows us to proceed. Of course, ***we will do that when we have a strategic partnership that allows us, to be able to finance the study.***" In other words, without Accelerated Approval Agenus lacked the financial capacity to begin Phase 3 tests.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

132. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about Agenus's business, operations, and prospects. Specifically, Defendants affirmatively misrepresented and/or failed to disclose to investors: that (i) Agenus did not have sufficient data to obtain Accelerated Approval of BOT/BAL for the treatment of patients with non–microsatellite instability–high (MSI-H)/mismatch repair–deficient (dMMR) metastatic colorectal cancer (mCRC) with no active liver involvement; (ii) Defendant Armen had been grossly exaggerating BOT/BAL's efficacy over the objections of high-ranking Agenus employees; (iii) Agenus lacked the ability to accelerate the development of its treatment candidates, and (iv) consequently, Agenus's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times. When the truth underlying each of the misleading statements set forth below was revealed to investors, the price of Agenus's securities plummeted.

A. Agenus Lacked Data Necessary to Obtain Accelerated Approval of BOT/BAL

133. Throughout the Class Period, Defendants materially downplayed to investors the extent of the risk that Agenus's clinical trial and study data for its BOT/BAL combination therapy was not sufficient to obtain Accelerated Approval of BOT/BAL for the treatment of patients with non–microsatellite instability–high (MSI-H)/mismatch repair–deficient (dMMR) metastatic colorectal cancer (mCRC) with no active liver involvement. Defendants' representations were false and misleading because Defendants knew, but did not disclose, that the limited Phase 2 clinical trial data Agenus possessed on BOT/BAL was nowhere near sufficient to show the durability and survival rates that the FDA needed to consider the BOT/BAL treatment for Accelerated Approval.

134. For example, Agenus's annual report on Form 10-K for 2022, which was filed with the SEC on March 14, 2023 and signed by Defendants Armen and Kaskin, stated "[o]ur lead program, botensilimab (AGEN1181), is ***advancing in multiple clinical programs which we have designed to support regulatory pathways for accelerated development with botensilimab as a monotherapy and in combination with balstilimab***."

135. By touting the Company's clinical programs for BOT/BAL, Defendants had an obligation to disclose the entire truth about those programs. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) rather than obtaining clinical trial data demonstrating a survival benefit, Defendants had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA. The statement was also misleading because Defendant Armen was disregarding what the FDA required for Accelerated Approval of BOT/BAL and thus the clinical programs were not "designed to support regulatory pathways for accelerated development."

136. On March 16, 2023, during a call with analysts and investors to discuss the Company's financial performance in 2022 (the "2022 Call"), Defendant Armen touted to investors, "Looking ahead, to 2023, we anticipate achieving important clinical milestones. ***On top of a year that has already demonstrated very impressive outcomes. That will set the foundation for a potential regulatory filing or potential botensilimab plus balstilimab within a period of time that will be in the best interest of patients based on robust data that can be justified***."

137. By touting that the Company had "set a foundation for a potential regulatory filing" for BOT/BAL, Defendants had an obligation to disclose the entire truth about that "foundation." Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) rather than obtaining clinical trial data demonstrating a survival benefit, Defendants had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

138. On August 23, 2023, the Company issued a press release entitled "Agenus Prioritizes Resources to Accelerate Registration and Commercialization of BOT/BAL Program in Multiple Cancers." The press release quoted Defendant Armen as stating that, "***By zeroing in on BOT/BAL, we expect to expedite regulatory approval and availability for healthcare providers and patients in need***. Our decision to streamline operations reflects our commitment to the success of these programs while optimizing shareholder value."

139. By touting the Company's focus on BOT/BAL, Defendants had an obligation to disclose the entire truth about their efforts in pursuit of Accelerated Approval of BOT/BAL. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) rather than obtaining clinical trial data demonstrating a survival benefit, Defendants had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants

had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA. The statement was also misleading because Defendant Armen was disregarding the information the FDA required for Accelerated Approval of BOT/BAL and thus the clinical programs which we have designed to support regulatory pathways

140. On November 7, 2023, Defendants held a call with analysts and investors to review the Company's performance in the third quarter of 2023 ("Q3 2023 Call"). During the scripted portion of the call, Defendant Armen touted that "With very limited options to treat patients with advanced colorectal cancer, ***the positive trends and lasting responses in our studies strengthen our conviction in BOT/BAL potential. Our top priority is obtaining BOT/BAL approval in MSS-CRC*** in order to allow patients access to this important IO treatment, offering them new hope, which does not exist today."

141. By touting the "positive trends and lasting response" and "conviction" in connection with BOT/BAL, Defendants had an obligation to disclose the entire truth about those "positive trends and lasting responses" and the Company's "conviction." Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) rather than obtaining clinical trial data demonstrating a survival benefit, Defendants had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

142. Later in the Q3 2023 Call, analyst Emily Bodnar of H.C. Wainwright asked, "when we may expect to see initial Phase II data for the MSS CRC study?" Defendant Armen deflected the question and assured investors that Agenus's Phase II studies would include data supporting a strong overall survival rate, saying "we have clearly disclosed the data on the first 70 patients, ***not because the rest of the data isn't satisfactory, but the rest of the data needs to be cleaned up and we need a little bit of work to do. But our look at the data both in the second call and in our Phase II studies indicate that we should have a sustainable response rate, perhaps even an improving response rate as we disclose and analyze these data for regulatory and beyond purposes***."

143. By touting the Company's Phase 2 data for BOT/BAL, Defendants had an obligation to disclose the entire truth about that data. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) Defendants could not obtain clinical trial data demonstrating a survival benefit because of the short length of the studies, and instead Defendants had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (ii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

144. Later, on the Q3 2023 Call, analyst Colleen Kusy from R.W. Baird asked, "And at the time of BLA submission [for BOT/BAL for MSS CRC], would you expect to have any sort of overall survival early data from this [Phase 2] study?" Defendant Yancey, Agenus's SGDA, responded: "We are obviously seeing that responses for patients and that response can be stable -- or better is translating to not only durable response, but very substantial overall survival. ***So I certainly expect that we'd be able to demonstrate a point estimates for response, durability of***

response for patients with stable disease or better and that is trending toward a survival benefit." Yancey also went on state that "***the time of submission is not a moment in time that's frozen*** because we will be required to provide updates on safety and efficacy during agency review. And that will allow time for additional maturation of the data set . . . ***So I think we have a very, very robust set of data to present to the agencies for their review***.

145. By touting the Company's durability and survival data, the data's robustness, and the Company's ability to supplement the data, Defendants had an obligation to disclose the entire truth about those programs. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) Defendants had not obtained clinical trial data demonstrating a survival benefit, Defendants had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; (ii) as Defendant Armen later admitted, "the FDA has very strict rules on not considering data post-submission of the package, and between the submission of the package and the meeting could be several months . . . . So even though we had more mature data by the time we had the actual meeting, this data wasn't being formally considered in their consideration of their guidance to us"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

146. Still later on the Q3 2023 Call, in response to a question from B. Riley analyst Mayank Mamtani, Defendant Armen emphasized that Agenus had the ability to demonstrate a sufficient survival benefit for preliminary approval of BOT/BAL for MSS CRC, stating in no uncertain terms that "of course, ***there are regulatory and other questions about do overall response rates translate to longer-term benefit. We know they do. We need to demonstrate that***

with numbers, but with CTLA-4 binding antibodies and ours is a multifunctional broad functioning molecule that binds the CTLA-4 as one of its five different activities, not just the center stage activity, but one of five different activities."

147. By electing to affirmatively comment on whether overall response rates translate to survival benefits in connection with BOT/BAL, Defendants had an obligation to disclose the entire truth about those programs. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) Defendants could not obtain trial data demonstrating a survival benefit given the shortness of Phase 2 trials and instead were assuming that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (ii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA. Defendant Armen's statement also created the impression in investors' minds that Defendants were relying on more than just their assumption that the FDA would accept their Defendants' assumption that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit."

148. On March 14, 2024, Agenus hosted an earnings call with investors and analysts to discuss the Company's Q4 and full year 2023 results (the "2023 Call"). During the scripted portion of the 2023 Earnings Call, Defendant Armen stated, in relevant part:

> In 2023, Agenus reached crucial milestones, particularly with our BOT/BAL program, a cornerstone of our operational focus. ***BOT/BAL therapy has undergone rigorous testing in over 900 patients, demonstrating promising activity in cancers that represent significant unmet medical needs, notably colon cancer, where we are poised for potential first approval***.
>
> ***

> As we stand on the threshold of a clinical and a critical phase in our regulatory journey, our focus is squarely on advancing activities for a potential accelerated approval filing. ***Our immediate efforts are directed towards ensuring that our development strategies align seamlessly with the FDA's rigorous standards***. In 2024, our primary objective is to pursue a global regulatory strategy for BOT/BAL in our fast track indication.

149. By touting the Company's clinical programs for BOT/BAL and work toward "ensuring that our development strategies align seamlessly with the FDA's rigorous standards" Defendants had an obligation to disclose the entire truth about those programs and work. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies, which covered majority of the "900 patients" were not powered appropriately to capture survival or durability data; (ii) Defendants could not obtain clinical trial data demonstrating a survival benefit given the shortness of the Phase 2 trials and instead had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA. The statement was also misleading because Defendant Armen was disregarding what the FDA required for Accelerated Approval of BOT/BAL and thus Agenus's "development strategies align seamlessly with the FDA's rigorous standards."

150. Later on the 2023 Call, 2023 Call, analyst Colleen Kusey of R. Baird asked, "What are some of the outstanding items do you think you need FDA feedback prior to the MSS CRC filing?" Defendant Armen responded that BOT/BAL's Phase 2 trials were:

> [D]esigned to address the project optimist questions. And so the question was for us, if we go to the agency and ask them a question in an abstract form. What is this? What is that? The answer is likely to be, well, when you have the data, come back to us, present it to us, and we'll give you an intelligent answer. And so ***in order to for us to be able to get to that point, we made a strategic decision, Colleen, that we would wait until all the data mature to the point where we had a compelling***

> ***package with to present to the FDA***. So that's the reason why we are waiting until the data matures, which will begin somewhat before the middle of this year."

151. By touting the Company's "strategic decision" to "wait until all the data mature," Defendants had an obligation to disclose the entire truth about the BOT/BAL data. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants could not obtain clinical trial data demonstrating a survival benefit given the shortness of Phase 2 trials, and instead Defendants had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

152. Later in the 2023 Call, analyst Matthew Phipps at Willaim Blair asked, when you said data in the second half from the Phase 2 colorectal study, do you think you'll have PFS data by that point?" Defendant Armen responded first, explaining that "PFS in these patients relative to OS is such a short interval difference that I think OS is the gold standard, PFS is much less so. Steven, Todd, do you have any comments on that?" Defendant O'Day then responded that, "yes, I mean, ***obviously, we'll have response rate, duration of response, PFS and preliminary survival in these patients as they mature over the course of the year from their last -- from when they were accrued. So obviously, it's a composite endpoint. But to Garo's point, clearly, response and duration of response is what drives and prolonged stable disease drive the survival curve***."

153. By touting the Company's clinical data for BOT/BAL, Defendants had an obligation to disclose the entire truth about that data. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) Defendants could not obtain clinical

trial data demonstrating a survival benefit given the shortness of Phase 2 studies, and instead assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (ii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

154. On April 12, 2024, the Company issued a press release entitled "Agenus Announces Updated Phase 1 Data and Progress on BOT/BAL Development in Metastatic MSS Colorectal Cancer." The press release apprised investors that, "***[p]ending planned meetings with the FDA, Agenus plans to submit a Biologics License Application (BLA) for BOT/BAL in refractory MSS CRC later this year and plans to present detailed Phase 2 efficacy results, including response durability and updated Phase 1 survival data, at a major medical conference in the second half of 2024. This growing body of clinical evidence underscores the significant potential of BOT/BAL to transform the treatment landscape for difficult-to-treat solid tumors***.

155. By touting the Company's Phase 1 and Phase 2 data for BOT/BAL, Defendants had an obligation to disclose the entire truth about those programs. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (i.e., Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants could not obtain clinical trial data demonstrating a survival benefit given the shortness of the Phase 2 studies, and instead had assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

156. On May 7, 2024, Agenus issued a press release announcing the Company's Q1 2024 results. In the press release, Defendant Armen touted that, "***[t]he BOT/BAL combination has consistently demonstrated deep and durable responses in 'cold' solid tumors, especially in our advanced studies of relapsed/refractory MSS CRC. With the promising results we have seen, and additional data from our ongoing Phase 2 study, we plan to engage with the FDA in the second half of 2024***. Pending the outcomes of these discussions, we aim to commence the submission of a Biologics License Application under the accelerated approval provision for BOT/BAL in refractory MSS CRC NLM."

157. By touting the Company's clinical programs for BOT/BAL, Defendants had an obligation to disclose the entire truth about those programs. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants could not obtain clinical trial data demonstrating a survival benefit because of the shortness of those trials and instead assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

158. Also on May 7, 2024, Defendants held a call with analysts and investors to discuss Agenus's first quarter 2024 performance (the "Q1 2024 Call"). On the call, analyst Emily Bodnar of H.C. Wainwright asked point blank, "could you confirm how many patients you've treated with BOT/BAL at the recommended Phase 2 dose across the Phase 1b and Phase 2 studies specifically

for MS CRC patients without? And your confidence, I guess, that you have enough efficacy data to support an accelerated approval?" Defendant Armen responded:

> First of all, as you may know, for the last almost 6 months, we have been intensively involved in pulling together the data from all the trials including tracking the maturity of the data, as Steven alluded to, to see how we can make a compelling package in an upcoming meeting with the FDA. And ***our conviction based on the data from all 3 cohorts, including the Phase 2 randomized study as well as the durability and maturity of the data is stronger today than it's ever before that we will maybe take compelling case. Of course, we cannot make a definitive statement until the outcome of the FDA meeting and we need to get their concordance on our ambition. But we are in an optimal state of preparedness with where we are right now and more developments and the progress on this will be coming forward in the next several weeks***.

159. By touting the Company's clinical programs for BOT/BAL and upcoming presentation to the FDA, including an "optimal state of preparedness," Defendants had an obligation to disclose the entire truth about those programs, the presentation, and their preparedness. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants could not obtain clinical trial data demonstrating a survival benefit because of the shortness of those trials and instead assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

160. Defendant O'Day then provided his response to the analyst's question as well, stating, "we're not going to get into the absolute specific numbers but we can -- what I can say is ***with the Phase 1 and the Phase 2 trial, we have 2 active doses and a significant number of patients on the combination of BOT/BAL in both the Phase 1 and the Phase 2 randomized trial***

that we think are supported with safety, efficacy and clinical pharmacology to discuss with an accelerated pathway given the unmet need in this setting."

161. By touting the Company's clinical programs and data for BOT/BAL, Defendants had an obligation to disclose the entire truth about those programs. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants could not obtain clinical trial data demonstrating a survival benefit because of the shortness of those trials and instead assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

162. Later on the Q1 2024 Call, analyst Mayank Mamtami from B. Riley Securities asked, "On the follow-up from the Phase 2, like you are at, I think, 14 months follow-up in the -- from the Phase 1. Is there a particular requirement or best practices in terms of how much follow-up you need to have from Phase 2? Or is that sort of subject to discussion?" Defendant Armen responded by falsely assuring analysts and investors that their data was sufficient with regard to Phase 2: "***the FDA has guidance that is based on historical precedents on the minimum follow***. ***But we have had significant input from our regulatory advisers on what that minimum should be***. Of course, ideally, we can wait 5 years but we're not going to do that. But the minimum enrollment in the Phase 2 ended in October 2023. And based on that, you can sort of extrapolate what the follow-up period will be between now and the potential FDA meeting."

163. By touting the Company's "significant input from our regulatory advisers," Defendants had an obligation to disclose the entire truth about that input. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that they had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

164. On May 16, 2024, Agenus issued a press release entitled "FDA Grants Agenus Type B End-of-Phase 2 Meeting to Discuss BOT/BAL Therapy for Relapsed or Refractory Metastatic Colorectal Cancer." The press release quoted Defendant O'Day touting that

> Our upcoming End of Phase 2 meeting with the FDA represents a significant milestone in the ongoing development of BOT/BAL for patients diagnosed with metastatic MSS CRC who do not have active liver metastases . . . . ***The results from our Phase 1 and Phase 2 studies contribute valuable insights into the potential of this therapy for managing a specific and challenging subgroup of colorectal cancer***. We remain dedicated to further exploring innovative immunotherapeutic strategies.

165. By touting the Company's clinical programs and data for BOT/BAL, Defendants had an obligation to disclose the entire truth about those programs. Defendants failed to fulfill this obligation because they misrepresented and/or failed to disclose that, (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants could not obtain clinical trial data demonstrating a survival benefit because of the shortness of those trials and instead assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit"; and (iii) Defendants had been advised by multiple executives, including the Company's own FDA submission team, that Agenus's data was insufficient to support an application for Accelerated Approval by the FDA.

B. Defendants Had Been Misrepresenting BOT/BAL's Efficacy and Potential

166. Throughout the Class Period, Defendants materially exaggerated the effectiveness and potential of BOT/BAL. Defendants' representations were false and misleading because Defendants made the representations knowing, based on repeated internal warnings, that their descriptions of BOT/BAL's unprecedentedness, "breakthrough" nature of treatment, durability, and overall survival were not scientifically supported and gave investors a false impression of the likelihood that the combination treatment could be successfully submitted for Accelerated Approval by the FDA.

167. Defendants misleadingly touted the efficacy of the BOT/BAL combination therapy from the very start of the Class Period. On January 23, 2023, Agenus issued a press release during pre-market hours "announc[ing] clinical data from the MSS CRC (microsatellite stable colorectal cancer) 70 patient cohort of a Phase 1b study of botensilimab (multifunctional Fc-enhanced anti-CTLA-4) in combination with balstilimab (anti-PD-1) in patients with chemotherapy and/or immunotherapy-resistant tumors." The press release quoted Defendant O'Day as stating:

> "***This data highlight the deep and durable responses achieved with botensilimab and balstilimab in advanced MSS CRC, underscoring remarkable benefit for these patients who have failed standard of care or other investigative therapies. With over 300 patients enrolled to date, botensilimab alone and in combination with balstilimab have demonstrated durable clinical responses across nine cold and treatment-resistant cancers***," said [Defendant] O'Day[.] "Our top priority is to advance this combination in global randomized trials with the intent to bring this important treatment to patients expeditiously."

168. Defendants' descriptions of "deep and durable" clinical responses were materially false and/or misleading because (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants had been repeatedly warned that their statements were misleading as to durability, overall survival, "breakthrough" and unprecedented nature of the BOT/BAL combination treatment; (iii) rather than heed those

warnings, Defendants had fired or laid off the employees objecting to Defendants' statements; and (iv) as a result, Defendants' statements misled investors as to the likelihood that BOT/BAL could be successfully submitted to the FDA for Accelerated Approval.

169. On March 14, 2023, Agenus issued a press release announcing the Company's Q4 and full year 2023 financial results ("2023 Release"). The press release quoted Defendant Armen as stating "With the ***growing body of data demonstrating robust, consistent, and durable efficacy signals*** from a trial of over 300 patients across nine metastatic, late-line cancers, we are expediting the expansion of our botensilimab/balstilimab development program in MSS CRC and other priority indications."

170. Defendants' statements in paragraph 169 above were materially false and/or misleading because (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants had been repeatedly warned that their statements were misleading as to the overall survival, and unprecedented nature of the BOT/BAL combination treatment; (iii) rather than heed those warnings, Defendants had fired or laid off the employees objecting to Defendants' statements; and (iv) as a result, Defendants' statements misled investors as to the likelihood that BOT/BAL could be successfully submitted to the FDA for Accelerated Approval.

171. On June 30, 2023, Agenus issued a press release entitled "ESMO GI Data: Agenus' Botensilimab/Balstilimab Combination Achieves ***Unprecedented Survival*** in Advanced Colorectal Cancer." The press release touted that "***The new data show substantial survival benefits and long-lasting responses*** for patients with non-MSI-H (microsatellite stable or non-microsatellite instability-high) metastatic colorectal cancer previously resistant to chemotherapy and/or immunotherapy."

172. Defendants' statements in paragraph 171 above were materially false and/or misleading because (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants had been repeatedly warned that their statements were misleading as to the overall survival, and unprecedented nature of the BOT/BAL combination treatment; (iii) rather than heed those warnings, Defendants had fired or laid off the employees objecting to Defendants' statements; and (iv) as a result, Defendants' statements misled investors as to the likelihood that BOT/BAL could be successfully submitted to the FDA for Accelerated Approval.

173. On May 9, 2023, Agenus an earnings call with investors and analysts to discuss the Company's Q1 2023 results (the "Q1 2023 Earnings Call"). During the scripted portion of the Q1 2023 Earnings Call, Defendant Armen stated, "In a diverse patient population of nearly 400 individuals, across nine solid tumor types, all of them had exhausted prior treatment options botensilimab has made significant strides in eliciting responses, ***offering renewed hope for those who have failed all other available treatments*** . . . . This is truly an impressive accomplishment considering the patient population involved. ***Notably many of these responses have proven to be durable responses. This is a critical factor in evaluating a treatment potential to transform patient's lives in a meaningful way***." Armen continued, "Even in hot tumors that have failed standard-of-care, including immunotherapy, of course, with or without chemotherapy, ***we are witnessing unprecedented responses***."

174. Defendants' statements in paragraph 173 above were materially false and/or misleading because (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants had been repeatedly warned that their statements were misleading as to durability, the overall survival, and unprecedented nature of the

BOT/BAL combination treatment; (iii) rather than heed those warnings, Defendants had fired or laid off the employees objecting to Defendants' statements; and (iv) as a result, Defendants' statements misled investors as to the likelihood that BOT/BAL could be successfully submitted to the FDA for Accelerated Approval.

175. On August 8, 2023, Agenus issued a press release announcing the Company's Q2 2023 results. The press release quoted Defendant Armen touting that "Botensilimab, alone or in combination with balstilimab, ***continues to display remarkable clinical activity*** . . . ***demonstrating great potential to revolutionize the role of immunotherapy in cancer treatment . . . . [o]ur data has demonstrated an unprecedented survival benefit*** over what has been reported for standard of care"

176. Defendants' statements in paragraph 175 above were materially false and/or misleading because (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants had been repeatedly warned that their statements were misleading as to the overall survival, and unprecedented nature of the BOT/BAL combination treatment; (iii) rather than heed those warnings, Defendants had fired or laid off the employees objecting to Defendants' statements; and (iv) as a result, Defendants' statements misled investors as to the likelihood that BOT/BAL could be successfully submitted to the FDA for Accelerated Approval.

177. On October 22, 2023, the Company issued a press release entitled "Agenus Unveils New and Updated Botensilimab Data in Colorectal, Pancreatic, Lung, Melanoma, and Sarcoma." In the press release, Defendant O'Day touted that "new and updated data underscore BOT's broad effectiveness across several advanced solid tumors, demonstrating its potential beyond first-generation immunotherapies and current treatments . . . . ***BOT's versatility, alone, in combination***

with BAL, or in combination with other standard of care therapies, in early and late-stage solid tumors, positions Agenus to transform cancer care, offering immense promise to patients."

178. Defendants' statements in paragraph 177 concerning BOT's ability to "transform cancer care" were materially false and/or misleading because (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants had been repeatedly warned that their statements were misleading as to the overall survival, and unprecedented nature of BOT/BAL; (iii) rather than heed those warnings, Defendants had fired or laid off the employees objecting to Defendants' statements; and (iv) as a result, Defendants' statements misled investors as to the likelihood that BOT/BAL could be successfully submitted to the FDA for Accelerated Approval.

179. On May 7, 2024, Defendants hosted an earnings call with investors and analysts to discuss the Company's Q1 2024 results (the "Q1 2024 Call"). During the scripted portion of the call, Defendant O'Day touted that "***Botensilimab in combination with Balstilimab has demonstrated deep and durable responses*** across a wide variety of poorly immunogenic or IO refractory solid tumors."

180. Defendants' statements in paragraph 179 above were materially false and/or misleading because (i) the Company's initial (*i.e.*, Phase 1) studies were not powered appropriately to capture survival or durability data; (ii) Defendants had been repeatedly warned that their statements were misleading as to the overall survival, and unprecedented nature of the BOT/BAL combination treatment; (iii) rather than heed those warnings, Defendants had fired or laid off the employees objecting to Defendants' statements; and (iv) as a result, Defendants' statements misled investors as to the likelihood that BOT/BAL could be successfully submitted to the FDA for Accelerated Approval.

C. Agenus Lacked the Ability to Accelerate the Development of Its Treatment Candidates

181. Throughout the Class Period, Defendants materially exaggerated Agenus's ability to produce or obtain approval of its treatment candidates, including BOT/BAL. Defendants' representations were false and misleading because Defendants knew, but did not disclose, that the Company routinely failed to pay vendors and suppliers, was forced to shut down manufacturing during the Class Period because of its failure to pay vendors and suppliers, and failed to maintain accelerated timelines in connection with seeking Accelerated Approval of BOT/BAL.

182. For example, the Company's 2022 10-K, filed with SEC on March 16, 2023 and signed by Defendants Armen and Klaskin stated that "delivering innovation with speed is critical for our future success, as drug development timelines in oncology shorten while product obsolescence rates climb. ***We believe our fully integrated, end-to-end capabilities from our artificial intelligence-powered VISION platform for novel target discovery, antibody generation, and cell line development to our cGMP manufacturing and clinical development and operations capabilities, together with a comprehensive and complementary portfolio will uniquely position us to produce novel therapies on accelerated timelines***." The 2022 10-K further stated that "[i]n addition to a diverse pipeline, we have assembled fully integrated end-to-end capabilities including novel target discovery, antibody generation, cell line development and cGMP manufacturing. ***We believe that these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard***."

183. The 2022 10-K further represented that, "we are pursuing clinical trials designed to strengthen the efficacy and safety signals demonstrated to date and ***that may support a potential filing for full approval and/or accelerated approval based on the magnitude of benefit demonstrated***" and separately "[o]ur lead program, botensilimab (AGEN1181), is ***advancing in***

multiple clinical programs which we have designed to support regulatory pathways for accelerated development with botensilimab as a monotherapy and in combination with balstilimab."

184. By affirmatively electing to describe and characterize Agenus's ability to "accelerate[] development" or "produce novel therapies on accelerated timelines," Defendants were required to disclose all the necessary facts to make their statements in paragraphs 182-83 above not misleading, including that Agenus lacked the necessary staff or plans to "accelerate" the development of its treatment candidates. Further, Defendants' statements in paragraphs 182-83 above were false and misleading on their face because Defendant Armen (i) forced his staff to implement accelerated timelines without any basis that were made up out of whole cloth, (ii) fired, laid off, or caused employees to quit so frequently that he impeded Agenus's ability to operate, and (iii) refused to pay vendors and suppliers, which resulted in manufacturing shutdowns.

185. Further, the 2022 10-K also attributed the Company's risk failing to accelerate production or approval of its product candidates, including BOT/BAL, to the FDA's capriciousness, rather than Agenus's habitual failure to pay vendors and manufacturing stoppages. For example, in a section entitled "Risk Factors," 2022 Form 10-K stated, "[w]e ***intend to utilize an accelerated approval approach*** for our product candidates given the limited alternatives for cancer treatments, but the ***FDA may not agree with our plans***."

186. The cautionary language in paragraph 185 above was a generic "catch-all" provision that was not tailored to Agenus's actual known risks with respect to its inability to employ an "accelerated approval approach." The warning was also misleading because it failed to disclose the material risks to the Company caused by its baseless timelines, failure to pay vendors, and manufacturing stoppages.

187. These misrepresentations continued in the Company's quarterly reports on Form 10-Q that were filed with the SEC. Each of the Q1, Q2 and Q3 2023 10-Q touted to investors that, "[i]n addition to a diverse pipeline, ***we have assembled fully integrated end-to-end capabilities*** including novel target discovery, antibody generation, cell line development and current good manufacturing practice ("cGMP") clinical manufacturing. We believe that ***these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard***."

188. By affirmatively electing to describe and characterize Agenus's ability to "accelerate[] development" or "produce novel therapies on accelerated timelines," Defendants were required to disclose all the necessary facts to make their statements in paragraph 187 above not misleading, including that Agenus lacked the necessary staff or plans to "accelerate" the development of its treatment candidates. Further, Defendants' statements in paragraph 187 above were false and misleading on their face because Defendant Armen (i) forced his staff to implement accelerated timelines without any basis that were made up out of whole cloth, (ii) fired, laid off, or caused employees to quit so frequently that he impeded Agenus's ability to operate, and (iii) refused to pay vendors and suppliers, which resulted in manufacturing shutdowns.

189. The 2023 10-K similarly averred that "[w]e believe ***our fully integrated, end-to-end capabilities*** for novel target discovery, antibody generation, and cell line development to our cGMP manufacturing and clinical development and operations capabilities, together with a comprehensive and complementary portfolio ***will uniquely position us to produce potential novel therapies on accelerated timelines***."

190. By affirmatively electing to describe and characterize Agenus's ability to "accelerate[] development" or "produce novel therapies on accelerated timelines," Defendants

were required to disclose all the necessary facts to make their statements in paragraph 190 above not misleading, including that Agenus lacked the necessary staff or plans to "accelerate" the development of its treatment candidates. Further, Defendants' statements in paragraph 190 above were false and misleading on their face because Defendant Armen (i) forced his staff to implement accelerated timelines without any basis that were made up out of whole cloth, (ii) fired, laid off, or caused employees to quit so frequently that he impeded Agenus's ability to operate, and (iii) refused to pay vendors and suppliers, which resulted in manufacturing shutdowns.

191. Further, the 2023 10-K also attributed the Company's risk failing to accelerate production or approval of its product candidates, including BOT/BAL, to the FDA's capriciousness, rather than Agenus' habitual failure to pay vendors and manufacturing stoppages. For example, in a section entitled "Risk Factors," the 2023 10-K asserted that the Company "***intend[s] to utilize an accelerated approval approach for our product candidates given the limited alternatives for cancer treatments, but the FDA may not agree with our plans***."

192. The cautionary language in paragraph 191 above was a generic "catch-all" provision that was not tailored to Agenus's actual known risks with respect to its inability to employ an "accelerated approval approach." The warning was also misleading because it failed to disclose the material risks to the Company caused by its habitual failure to pay vendors and manufacturing stoppages.

193. The misrepresentations continued into 2024 as The Company's Form 10-Q for the quarterly period ended March 31, 2024 was filed with the SEC on May 7, 2024 and signed by Defendant Klaskin and stated ""[i]n addition to our diverse pipeline, ***we have established fully integrated capabilities*** encompassing novel target discovery, antibody generation, cell line development, and good manufacturing practice (GMP) manufacturing. We believe ***these***

integrated capabilities enable us to develop and, if approved, commercialize novel candidates on accelerated timelines compared to industry standards."

194. By affirmatively electing to describe and characterize Agenus's ability to "accelerate[] development" or "produce novel therapies on accelerated timelines," Defendants were required to disclose all the necessary facts to make their statements in paragraph 194 above not misleading, including that Agenus lacked the necessary staff or plans to "accelerate" the development of its treatment candidates. Further, Defendants' statements in paragraphs 194 above were false and misleading on their face because Defendant Armen (i) forced his staff to implement accelerated timelines without any basis that were made up out of whole cloth, (ii) fired, laid off, or caused employees to quit so frequently that he impeded Agenus's ability to operate, and (iii) refused to pay vendors and suppliers, which resulted in manufacturing shutdowns.

D. False and Misleading Statements in the Certifications Attached to Agenus's Quarterly and Annual Reports During the Class Period

195. Appended as exhibits to the Company's 2022 and 2023 10-Ks were certifications signed by Defendants Armen and Klaskin pursuant to the Section 302 of the Sarbanes-Oxley Act of 2002 ("SOX"), in which each of Defendants Armen and Klaskin certified that they had "reviewed the annual report on Form 10-K of Agenus Inc. [and] . . . [b]ased on my knowledge [the] report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" and that each of the 2022 and 2023 10-Ks "fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act" and "fairly presents, in all material respects, the financial condition and results of operations" of Agenus.

196. Each of the above statements excerpted from the exhibits to Agenus's 2022 and 2023 10-Ks were materially false and misleading because each of the 2022 and 2023 10-Ks "omitted to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and did not "fully comply with the requirements of Section 13(a) or 15(d) of the Exchange Act" because the 2022 and 2023 10-Ks failed misrepresented and/or failed to disclose that: (i) Agenus did not have sufficient data to obtain Accelerated Approval of BOT/BAL for the treatment of patients with non–microsatellite instability–high (MSI-H)/mismatch repair–deficient (dMMR) metastatic colorectal cancer (mCRC) with no active liver involvement; (ii) Defendant Armen had been grossly exaggerating BOT/BAL's efficacy over the objections of high-ranking Agenus employees; (iii) Agenus lacked the ability to accelerate the development of its treatment candidates, and (iv) consequently, Agenus's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times.

197. Appended as exhibits to each of the Company's Q1 2023 10-Q, Q2 2023 10-Q, Q3 2023 10-Q, and Q1 2024 10-Q were certifications signed by Defendants Armen and Klaskin pursuant to the Section 302 of SOX, in which Defendants Armen and Klaskin certified that "[t]he [Q3 2021 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act] (15 U.S.C. 78m)" and "fairly present[], in all material respects, the financial condition and results of operations" of Agenus. These statements were materially false and misleading because each of the Q1 2023 10-Q, Q2 2023 10-Q, Q3 2023 10-Q, and Q1 2024 10-Q failed to disclose that: (i) Agenus did not have sufficient data to obtain Accelerated Approval of BOT/BAL for the treatment of patients with non–microsatellite instability–high (MSI-H)/mismatch repair–deficient (dMMR) metastatic colorectal cancer (mCRC) with no active liver involvement; (ii) Defendant

Armen had been grossly exaggerating BOT/BAL's efficacy over the objections of high-ranking Agenus employees; (iii) Agenus lacked the ability to accelerate the development of its treatment candidates, and (iv) consequently, Agenus's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times.

The Truth Emerges

198. Defendants statements' were revealed to be false and misleading, and the risks concealed by those statements emerged, upon the publication of the EOP2 Release on July 18, 2024. In that release, Defendants announced that the FDA advised against submitting an application for Accelerated Approval for BOT/BAL, which increased the likelihood that a competitor would obtain approval earlier (thereby ruining the drug's market potential) and that there was a strong possibility that Agenus would not have the funds to conduct Phase 3 trials.

199. The EOP2 Release also revealed a number of facts that blind-sided investors. First, interim topline data from the Phase 2 study showed that patients treated with the 75-mg dose of BOT/BAL experienced an "overall response rate" ("ORR") of 19.4%, and patients given the 150-mg dose of BOT/BAL experienced an ORR of only 8.2%, even though there was no evidence of toxicity from the higher dose and the maximum-tolerated dose was not reached. This meant that a 150mg dose of BOT/BAL was less than half as effective as a 75mg dose, even though the larger dose did not harm the patient, which threw into serious doubt BOT/BAL's long term effectiveness. Further, the interim Phase 2 data Defendants presented to the FDA was not even complete in an interim sense, as two class members had not participated in the clinical trial long enough for the FDA to credit their data.

200. On this news, Agenus's stock price fell $10.43 per share, or 58.83%, to close at $7.30 per share on July 18, 2024.

201. Journalists and analysts immediately attributed the share price decline to the revelations of FDA's finding in the EOP2 meeting. For example, Zacks Equity Research published an article on July 19, 2024 entitled, "Agenus (AGEN) Tanks on Colorectal Cancer Study Interim Data." The article stated that "Shares of Agenus Inc. AGEN plunged 58.8% on Jul 18 after the company announced the outcome of its end-of-phase II (EOP2) meeting with the FDA regarding the accelerated development of its immunotherapy combination botensilimab (BOT) and balstilimab (BAL)." Similarly, on July 18, 2024, analyst Emily Bodnar of H.C. Wainwright downgraded Agenus to "Neutral" and set a $9 price target for the shares, down from $40.

202. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

SCIENTER ALLEGATIONS

203. As set forth above, Defendants each had scienter as to the false and misleading nature of their statements because they each knew or, at a minimum, recklessly disregarded the facts described in the Substantive Allegations and Materially False and Misleading Statements sections above, for the following reasons.

a. Defendants had a motive for their fraud. Defendants caused Agenus to sell $84.4 million in shares in ATM offerings 2023, including sales of $20.3 million in Q2 2023, as well as $24.4 million in shares in ATM offerings between January 1, 2024 through March 8, 2024. These ATM offerings occurred as Agenus was preparing to present BOT/BAL to the FDA to gauge the agency's interest in an application for Accelerated Approval, and the Company reaped total net proceeds totaling $149.8 million in much needed capital.

b. Defendants had been confronted by multiple Agenus employees about the fact that there was not sufficient clinical trial data to support an accelerated approval application for BOT/BAL. In fact, Defendant Armen responded, "who cares about FDA, they can't stop us" and "we're going to submit with what we have because this is a breakthrough and they should not deny it," which at a minimum reflects severe recklessness.

c. Defendant Armen effectively admitted that, rather than present clinical trial evidence of a survival benefit, Defendants instead assumed that "any trial that is an IO-IO trial that binds to CTLA-4 and shows significant overall response rates always translates to survival benefit."

d. Defendant Armen evaded direct questions from analysts regarding BOT/BAL Phase 2 data.

e. Defendant O'Day got "the final numbers" on the studies, spoke regularly about the regulatory process, and was "constantly looking at data."

f. Defendants repeatedly fired Agenus employees who confronted them about the insufficiency of data supporting an application for Accelerated Approval of BOT/BAL and Defendants' misrepresentations concerning the BOT/BAL combination therapy.

g. Defendants were responsible for speaking with FDA representatives and knew non-public clinical data for BOT/BAL.

h. Defendant Armen was hostile to the FDA, which suggests that he was recklessly disregarding the FDA's requirements when addressing investors.

i. Defendant Armen had a pattern and practice of refusing to pay vendors.

j. Defendants Armen and Klaskin signed certifications attached to SEC filings which they knew contained material misstatements.

204. In addition to the above allegations, which on their own create a strong inference of scienter, additional factors support a strong inference of the Individual Defendants' scienter, including: (i) Defendants Armen, Klaskin, O'Day's, and Yancey's high-level positions within Agenus, (iii) that the misstatements and omissions of material facts concern Agenus's core operations, about which the Individual Defendants were repeatedly questioned and spoke; and (iii) corporate scienter.

A. <u>Individual Defendants' High-Level Positions Within Agenus</u>

205. Defendant Armen was CEO and Chairman of Agenus at all relevant times. Agenus identified Defendant Armen as an "Executive Officer" of the Company during the Class Period. As Agenus's CEO, Defendant Armen was the head of Agenus's management and operations teams. Defendant Armen, by virtue of his responsibilities and activities as CEO, was privy to all

material information concerning the Company's manufacturing capabilities, development of BOT/BAL, interactions with the FDA, BOT/BAL clinical trials and studies, the EOP2 meeting, Agenus's vendor payment practices, the termination of Agenus employees.

206. Defendant Klaskin was VP Finance at Agenus at all relevant times. Agenus identified Defendant Klaskin as an "Executive Officer" of the Company during the Class Period. Defendant Klaskin, by virtue of her responsibilities and activities as VP Finance, was privy to all material information concerning the Company's manufacturing capabilities, development of BOT/BAL, interactions with the FDA, BOT/BAL clinical trials and studies, the EOP2 meeting, and Agenus's vendor payment practices.

207. Defendant O'Day was CMO of Agenus at all relevant times. Agenus identified O'Day as an "Executive Officer" of the Company during the Class Period. By virtue of his responsibilities and activities as CMO, Defendant O'Day was privy to all material information concerning the Company's manufacturing capabilities, development of BOT/BAL, interactions with the FDA, BOT/BAL clinical trials and studies, and the EOP2 meeting.

208. Defendant Yancey was Agenus's SGDA from at least November 2023 onward. By virtue of his responsibilities and activities as SGDA, Defendant Yancey was privy to all material information concerning the Company's manufacturing capabilities, development of BOT/BAL, interactions with the FDA, BOT/BAL clinical trials and studies, and the EOP2 meeting.

B. Importance of BOT/BAL to Agenus

209. The fraud alleged herein relates to the core business and operations of Agenus so knowledge of the fraud may be imputed to Defendants. Throughout the Class Period, the BOT/BAL combination therapy for treatment of MSS CRC was Agenus's most important product and essential to the Company's survival. For example, early in the Class Period, during the 2022

Call, Defendant O'Day reminded investors and analysts that "advancing the clinical development of botensilimab and balstilimab remains our top priority."

210. Indeed, on August 23, 2023, less than halfway through the Class Period, Defendants announced that Agenus was laying off 25% of its workforce and temporarily ceasing all preclinical and clinical programs not related to BOT/BAL specifically so that the Company could focus all of its resources on obtaining Accelerated Approval of BOT/BAL.

211. Defendants emphasized to investors that the Company was focusing on BOT/BAL development at the expense of other pipeline products. Each of Agenus's Q3 2023 10-Q, 2023 10-K, and Q1 2024 10-Q informed investors that "[i]n August 2023, ***we prioritized and focused our resources to accelerate the development, registration, and commercialization of our lead asset postponing all preclinical and other clinical programs*** and reducing our workforce by approximately 25%." These touts of Defendants' focus on BOT/BAL continued on the 2023 Call, Defendant Armen assured investors that "***This year, a paramount objective for us is to present a compelling data package to the FDA***, seeking their consent to initiate the filing of our biologics license application." Finally, on the Q1 2024 Call, Defendant Armen left no doubt as to the Company's focus, emphasizing to an analyst that, '***I understand that we are absolutely fixated on CRC right now, because that is our focus for our first potential approval. So everything else is a little less of a priority***."

212. Accordingly, it is appropriate to presume that Defendants were apprised of, had access to, or had actual knowledge of all material information related to Agenus and the BOT/BAL combination treatment during the Class Period, including the material information that was improperly withheld and/or misrepresented to investors.

213. Further, by virtue of their receipt of information reflecting the true facts regarding Agenus's operations and its marketplace, as well as their control over and/or receipt of the Company's materially misleading misstatements and/or their associations with the Company that made them privy to confidential proprietary information concerning Agenus, the Individual Defendants were active and culpable participants in the fraudulent scheme alleged herein. The Individual Defendants knew of and/or recklessly disregarded the falsity and misleading nature of the information, which they caused to be disseminated to the investing public. The fraud as described herein could not have been perpetrated without the knowledge and/or recklessness and complicity of personnel at the highest level of the Company, including the Individual Defendants.

C. Corporate Scienter

214. The allegations above also establish a strong inference that Agenus as an entity acted with corporate scienter throughout the Class Period, as its officers, management, and agents, including, but not limited to, the Individual Defendants, had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing Agenus's true operating condition and present and expected financial performance from the investing public. By concealing these material facts from investors, Agenus maintained and/or increased its artificially inflated common stock prices throughout the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

215. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise

acquired Agenus securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

216. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Agenus securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Agenus or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

217. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

218. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

219. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Agenus;

- whether the Individual Defendants caused Agenus to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Agenus securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

220. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

221. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Agenus securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Agenus securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

222. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

223. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

224. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

225. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

226. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Agenus securities; and

(iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Agenus securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

227. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Agenus securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Agenus's finances and business prospects.

228. By virtue of their positions at Agenus, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

229. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Agenus, the Individual Defendants had knowledge of the details of Agenus's internal affairs.

230. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Agenus. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Agenus's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Agenus securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Agenus's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Agenus securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

231. During the Class Period, Agenus securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Agenus securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Agenus securities was substantially lower than the prices paid by Plaintiff and the other

members of the Class. The market price of Agenus securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

232. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

233. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

234. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

235. During the Class Period, the Individual Defendants participated in the operation and management of Agenus, and conducted and participated, directly and indirectly, in the conduct of Agenus's business affairs. Because of their senior positions, they knew the adverse non-public information about Agenus's misstatement of income and expenses and false financial statements.

236. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Agenus's financial condition and results of operations, and to correct promptly any public statements issued by Agenus which had become materially false or misleading.

237. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and

public filings which Agenus disseminated in the marketplace during the Class Period concerning Agenus's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Agenus to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Agenus within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Agenus securities.

238. Each of the Individual Defendants, therefore, acted as a controlling person of Agenus. By reason of their senior management positions and/or being directors of Agenus, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Agenus to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Agenus and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

239. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Agenus.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: February 7, 2024

Respectfully submitted,

POMERANTZ LLP

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on February 7, 2024.

/s/ Brian Calandra
Brian Calandra